ILLINOIS DEPARTMENT OF Healthcare and Family Services

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Drug Utilization Review Board
Meeting Summary
September 20, 2017

The Drug Utilization Review (DUR) Board met on Wednesday, September 20, 2017, 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; Tim Lehan, BSPharm; Anitha Nagelli, PharmD, M.Ed, Vice-chairperson; Bedrija Nikocevic, PharmD; Christopher Schriever, PharmD, MS; John E. Tulley, MD.

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

Interested parties: Dan Coleman, Merck; Joe Cirrincione, Otsuka; Lil Herrera, PharmD candidate, UIC College of Pharmacy (COP); Mindy Ho, PharmD candidate, COP; Keith Huff, Novartis; Michael LaFond, Abbvie; Danielle Leonard, Johnson & Johnson; Scott Mills, Allergan; Brenda Nunnally, AstraZeneca; Kenneth Park, PharmD candidate, COP; Awni Swais, Shire.

*Attendance via teleconference

Call to Order. Anitha Nagelli, PharmD, called the meeting to order on September 20, 2017 at 8:33 am.

Welcome new members and overview of DUR Board activities. Christina Petrykiw, PharmD, welcomed two new members to the DUR Board, pharmacists Bedrija Nikocevic, PharmD from the Chicagoland area and Christopher Schriever, PharmD, MS, from the Rockford area. A brief overview of the activities of the Drug and Therapeutics Committee and the DUR Board, which are both advisory to HFS, was provided. Differences between prospective and retrospective DUR as well as available DUR tools were reviewed.

Agenda, conflict of interest review, and approval of May 17, 2017 meeting minutes. Illinois DUR Board members had no changes to the May 17, 2017 minutes. Tim Lehan, BSPharm, made a motion, seconded by John Tulley, MD, and the DUR Board unanimously approved the May 17, 2017 minutes. Christina Petrykiw, PharmD requested moving the retrospective ADHD medications in children discussion after the prospective Adult ADHD criteria item on the agenda to facilitate the benzodiazepine discussion. Bedrija Nikocevic, PharmD, made a motion, seconded by Tim Lehan, BSPharm, and the DUR Board unanimously approved the September 20, 2017 agenda changes. Anitha Nagelli, PharmD, requested DUR Board members recuse themselves from discussion if a conflict of interest exists and to update their Conflict of Interest form if needed. Tim Lehan, BSPharm asked whether there were any restrictions for DUR Board members regarding talking with representatives of pharmaceutical companies. Christina Petrykiw, PharmD noted Open Meeting Act provides guidance related to discussion among Board members regarding committee business. Dr. Goyal noted that contact should be declared if there is a conflict of interest. Tim Lehan, BSPharm noted that the issue was not related to the agenda. Mary Lynn Moody, BSPharm suggested providing more information regarding circumstances to HFS after the meeting and that this topic can be included on a future agenda if needed.

HFS Bureau of Professional and Ancillary Services report. Patricia Steward, BSPharm, stated that HFS had nothing to report for this meeting.

Prospective Drug Utilization Review

Preferred Drug List (PDL) status updates. Christina Petrykiw, PharmD, informed DUR Board members that effective July 1, 2017 the 40-mg strength of fluoxetine capsules and the medication pregabalin (Lyrica) became preferred and were added to the PDL. The FDA-approved indications for pregabalin include pain due to diabetic peripheral neuropathy, postherpetic neuralgia, fibromyalgia, and spinal cord injury neuropathic pain. Pregabalin is also approved for adjunctive use in adults with partial onset seizures.

Adult Attention Deficit Hyperactivity Disorder (ADHD) criteria. Christina Petrykiw, PharmD, provided an overview of ADHD, highlighting how it differs from pediatric ADHD in terms of clinical course, diagnostic criteria, symptoms, and management per British ADHD guidelines and US practice recommendations. Importantly, unlike pediatric ADHD, pharmacologic therapy is used first and cognitive therapy is second-line. Stimulants are first-line therapy, primarily methylphenidate modified-release formulations. Atomoxetine is used when stimulants prove ineffective or are not tolerated, are contraindicated, or in the presence of anxiety or if risk of misuse/diversion exists. Third line therapy includes bupropion, tricyclic antidepressants, guanfacine, clonidine, and/or modafanil. History of cardiac death in first-degree relatives or cardiovascular concerns and exercise intolerance dictate need for cardiac exams before start of ADHD medications. At least 96% of 45 state Medicaid programs have criteria in place for stimulant use in adults. Appropriate use is managed by definitions of adult age, PDL status, quantity or dose limits, therapeutic duplication edits, diagnosis edits, and FDA-labeled indications and dosing. Some states deny medications if the Medicaid participant has a history of substance abuse. A patient informed consent document is required to ensure patients and prescribers comply with state and federal controlled substance laws. Informed consent documents address harm/side effects, misuse potential, safe use alone or with other medications/substances, sharing controlled substances being a felony, using one regular prescriber, agreement for therapy de-escalation with development of anxiety or panic attacks, and need for adherence with prescription without self-adjustment of doses due to potential adverse effects with increasing or abrupt decreasing of medication. Donna Clay, BSPharm, reviewed the initial and renewal HFS Adult ADHD criteria that incorporate diagnostic, concomitant medication, and Illinois Prescription Monitoring Program reviews. Informed consent for treatment of stimulants, as well as recent urine drug screens and confirmation of employment or academic enrollment are required. Approval length corresponds to academic calendars or 6 months if employed. DUR Board members asked why adult age was 19 in Illinois and were informed that this related to usually being out of high school by that time. Bedrija Nikocevic, PharmD, noted that it would be helpful for pharmacists to know that informed consent paperwork was needed, so that the pharmacist would be able to encourage the patient and prescriber to provide the information. Dr. Nikocevic asked about situations where the ADHD was too severe to maintain schoolwork or employment. Donna Clay, BSPharm noted that requests are reviewed individually with prescriber input, which addresses exceptions if needed. Dr. Laff mentioned that in her pediatric practice children are seen to age 21 and that it may be difficult to suddenly obtain a specialist re-evaluation after being treated previously without that requirement. Dr. Laff asked for clarification about urine drug screen and it was confirmed that the expectation of a positive screens depends on whether it is an initial or renewal prior authorization request. Per Dr. Goyal's request it was confirmed that prior authorization is currently required in children less than 6 years of age and in adults 19 years of age and older. The intent is to next roll-out criteria for pediatric age groups between 7 and 18 years of age. Dr. Goyal asked if it were possible to create a seamless policy from childhood through adulthood since there are concerns about ensuring appropriate diagnosis and use in all patients. High numbers of prescriptions for ADHD are seen in the Medicaid population. He underscored that delay of implementation of the Four Prescription Policy for children may be contributing to lack of review for pediatric patients. Abrupt discontinuation at a particular age since evaluation has not been done can lead to symptom exacerbation and withdrawal. Dr. Laff noted that practitioners may see the brief Conner scale advertised and can be using it for diagnosis and treatment initiation without obtaining a full psychiatric evaluation. There is also fear of prescribing due to adverse reactions. Evaluation helps ensure that medications are not prescribed inappropriately in patients with comorbidities. Donna Clay, BSPharm, agreed that criteria are needed for the 6-18 year old age group. Adult criteria were created first due to greater risk of potential misuse in adults. Dr. Laff stated that in some southern Illinois areas access to a specialist is difficult because of lack of local providers, need to travel far to see a specialist, as well as 6-month waiting periods to get a specialist appointment. Mary Lynn Moody, BSPharm, mentioned that HFS is looking for alternative mechanisms, such as the DocAssist prescriber peer consult for areas without specialists. Dr. Goyal noted that telepsychiatry rules have been implemented and will provide another option in these cases. Dr. Laff agreed that these could help and noted other issues are parental resistance/problem acknowledgement and need to educate prescribers. Dr. Nikocevic suggested incorporating a grace

period, perhaps of 6 months, for children who have transitioned to adulthood to obtain the consult, but be able to get medications in the interim period. Donna Clay, BSPharm noted that frequently since an approval is in place, nothing happens until a denial is received, but perhaps some type of shorter interim period can be incorporated. Dr. Goyal requested Prior Authorization staff develop criteria for the 6-18 year old group and present a full set of criteria that can align ADHD medical and psychiatric management for the full age spectrum within 6 months. Dr. Nikocevic noted that pharmacists are often not aware of what is needed when a medication is denied requiring prior authorization. The duration of a grace period would need to be communicated. Requirements are currently shared with the prescriber who has all of the patient information necessary to support appropriate clinical use. Dr. Nagelli recommended implementation of a transition fill edit so no break in therapy occurs for patients in a transition period. Dr. Tulley made a motion to use currently developed criteria for children less than 6 and adults in the interim until the full age spectrum criteria are presented. Dr. Laff and Tim Lehan, BSPharm seconded the motion and the DUR Board members unanimously approved use of current criteria until criteria for the full age spectrum are presented.

ADHD and DocAssist update. Mary Lynn Moody, BSPharm, provided an update of the current status of the University of Illinois at Chicago Department of Psychiatry DocAssist program review of HFS pediatric participants with ADHD. DocAssist is using Illinois criteria for ADHD drug dosing in children that were adapted from the Washington state age group dosing criteria. A review of 61,301 patient records identified that approximately 1% of the stimulant prescriptions had doses exceeding the criteria. This reflected 144 individual patients, eight of whom were receiving more than one product strength. Three percent of the children were 5 years of age, 10% were 6 years of age, 32% were 7 years of age, and 55% were 8 years of age. DocAssist has completed review and reached out to prescribers of all of the 5- and 6-year old children. In some cases, the DocAssist recommendation was to change the medication because the patient had a different underlying diagnosis that should be treated. At least 72% of the DocAssist recommendations were accepted. Currently DocAssist is reviewing the 7 year old children. At least 55% of the reviews have been completed and up to 66% of the recommendations were accepted to date. Ways to streamline this slow process are being identified. Prior Authorization is working with DocAssist to prioritize which participants should be reviewed first. Periodic updates will be provided to the DUR Board regarding this program.

Benzodiazepine edits. Christina Petrykiw, PharmD, provided an overview of benzodiazepine FDA-approved indications, HFS usage overall and by agent, current Illinois benzodiazepine edits, the benzodiazepine prescriber outreach within the Four Prescription Policy, and prior authorization criteria in other Medicaid state programs. Benzodiazepines are controlled substances due to their potential for physical/psychological dependence. HFS has identified overutilization and long-term, non-acute use of benzodiazepines. Physiologic dependence can occur within a few weeks of habitual use, in particular with higher doses. The most used benzodiazepines by HFS participants are alprazolam, clonazepam, and lorazepam. Since 2013, there has been about a 2% increase in clonazepam claims and a 1-2% decrease in alprazolam/lorazepam claims. Of the patients filling clonazepam, about 12% had a seizure diagnosis in 2016 in the HFS medical claims database, thus use of clonazepam appears to be primarily for other indications. Currently most of the benzodiazepine generic formulations are preferred, so claims are paid, unless the claim is stopped by an edit, for example, the Four Prescription Policy edit. Benzodiazepine requests reviewed within the Four Prescription Policy are approved about 64% of the time, with denials primarily due to lack of first-line therapy for the treatment of chronic anxiety. At least 36,687 individualized prescriber faxes have been sent since December 2012 educating about appropriate benzodiazepine prescribing. States have used more than one criteria, including Preferred Drug List status, prior authorization requirements, daily/monthly quantity limits, age criteria, duration of therapy limits, indication-based limits, history of substance abuse edits, duplicate therapy edits, and step therapy requiring non-pharmacologic and/or first-line medication therapy for given indications to help ensure appropriate benzodiazepine utilization. Some states have implemented edits denying benzodiazepine therapy in presence of opioid, stimulant, muscle relaxant, barbiturate, and/or medication-assisted therapy for addictions. A few states are using cumulative diazepam equivalent daily doses as a prior authorization criteria. Some states allow a maximum of 3 tablets daily for all or select benzodiazepines. Duration of therapy is based on indication being treated in several states, while some states require prior authorization only after a short time period of 2-4 weeks. A few states require prior authorization for all benzodiazepines, others for only select agents (alprazolam, clonazepam, lorazepam, diazepam) or dosage forms. In general, long-term benzodiazepine monotherapy is discouraged. Contraindications to benzodiazepine therapy include pregnancy and presence of medical conditions (sleep apnea, chronic obstructive pulmonary disease) or medications where benzodiazepine-induced respiratory depression could worsen current respiratory status. The DUR Board members discussed potential options to improve benzodiazepine utilization in HFS covered participants. Bedrija Nikocevic, PharmD, voiced concern regarding use of automatic denials if participants had an appropriate reason for

benzodiazepine use. Prior authorization staff noted that approval can be given if after review usage is deemed appropriate. DUR Board members asked whether the system can allow automatic approval if certain ICD-10 diagnostic codes were present in the HFS medical claims database. There is an opportunity to require review for all benzodiazepines, not just for those claims that hit for the Four Prescription Policy, a quantity override, or a non-preferred dosage form. Other options include allowing short-term approval for initial prescriptions. Concern was voiced about requiring approval for all benzodiazepines and patients needing a benzodiazepine during a weekend. Christina Petrykiw, PharmD, reminded everyone that pharmacies can provide and get paid for a 72-hour supply. Another option discussed was use of a maximum 14-day supply for an initial prescription. Currently prior authorization approvals do note duration of approval. Bedrija Nikocevic, PharmD, noted that unless the claim is denied, pharmacy staff usually do not read messages coming back from the insurer. Denials require following instructions for prior authorization for the insurer, so messages to the provider are then read. Anitha Nagelli, PharmD, questioned whether the new system can do a bi-directional edit that would allow the pharmacist to read the denial and override it when appropriate. Patty Stewart, BSPharm, will explore capabilities for some of the discussed options with the new system vendor. Dr. Tulley noted that some of these options apply to patients newly starting benzodiazepine therapy, but prescribers often inherit patients who have been on long-term benzodiazepine therapy with multiple concomitant therapies. Support was voiced for edits that address duplicate therapy and inappropriate concomitant therapy. Anitha Nagelli, PharmD, asked which HFS age groups were using benzodiazepines the most. Dr. Tulley made a motion to allow DUR Board members to consider all options until the next meeting, rather than make edit decisions now. The motion was seconded by Bedrija Nikocevic, PharmD, and unanimously approved by the DUR Board.

Retrospective Drug Utilization Review

Benzodiazepine use in patients filling narcotics. Christina Petrykiw, PharmD provided updated retrospective information DUR Board members had requested regarding concomitant benzodiazepine and narcotic use in participants who filled both a narcotic and benzodiazepine monthly in calendar year 2016. Alprazolam was the primary benzodiazepine and combination hydrocodone with acetaminophen was the primary opioid filled. Approximately 8% of patients filling the combination had a seizure indication in the HFS medical claims database: 56% of these were taking alprazolam which does not have an FDA-approved seizure indication, 25% were filling clonazepam, and about 6% each were filling diazepam, lorazepam, or 2-3 benzodiazepines during the year. Approximately 41% of patients filling both therapies were taking first-line therapy for chronic anxiety- a SSRI-SNRI. Approximately 8% were filling a tricyclic antidepressant, 16% were filling gabapentin, and < 1% were filling mirtazapine, all of which have been used off-label to treat anxiety. Approximately 4% of patients were filling buspirone and 2% were filling hydroxyzine, which are both indicated for the management of anxiety. About 12% of the patients are using combinations of a SSRI/SNRI with another medication to treat anxiety and concomitant conditions. For pain, 77% of the participants were using one or a combination of medications besides opioids to treat pain: a nonsteroidal anti-inflammatory (26%), the SNRI duloxetine (2%), tricyclic antidepressant which is used off-label for pain (8%), gabapentin (16%), pregabalin (< 1%), and a skeletal muscle relaxant which is indicated for treatment of spasms (25%). The most common combination was a muscle relaxant and NSAID along with an opioid (7%). Of the participants filling both medications for 12 months, less than 1% were in a long-term care facility and about 3% had a history of substance use or requirement to only use one prescriber/pharmacy. The majority of participants filled both medications at one pharmacy (73%), some filled both medications or only the opioid regularly at the same 2 pharmacies (13% each), few filled benzodiazepines at 2 pharmacies (3%), and 1% of participants filled each drug at 2 different pharmacies. In terms of prescribers, 43% of participants filling both medications monthly have one prescriber for the opioid and one prescriber for the benzodiazepine and 29% have the same prescriber for both medications. Overall, 36% of participants filling benzodiazepines and opioids monthly have more than one prescriber for narcotics only (19%), benzodiazepines only (4%), or more than 3 different prescribers for each medication (13%). The DUR Board members were reminded of the FDA Black Box warning issued August 2016 regarding increased risk of potentially fatal respiratory depression when combining opioids with benzodiazepines. If both medications are prescribed together, dosages and durations of therapy should be the minimum to achieve clinical effect. Christina Petrykiw, PharmD, announced that the State of Illinois Opioid Action Plan was released September 2017. The overall goal to decrease opioid-related deaths and safer prescribing and dispensing priorities were reviewed. Combination opioid and benzodiazepine prescribing is one of the highlighted unsafe practices. One of the strategies to decrease high-risk opioid prescribing includes decreasing the volume of inappropriate and high-risk opioid prescribing, including combinations of opioids with benzodiazepines. The DUR Board was tasked with incorporating this information as they consider benzodiazepine-related edits to recommend for implementation. Considerations include implementation of an edit for select or all benzodiazepines

with an opioid, edit for select or all opioids with a benzodiazepine, denials for contraindicated combinations or use in certain disease states, duration of therapy edits for benzodiazepines, opioids, or the combination, prescriber outreach, and educational items regarding concomitant therapy.

Education

Benzodiazepines. Christina Petrykiw, PharmD, informed DUR Board members of benzodiazepine-related prescriber initiatives launched within the last year by New York City, the state of Pennsylvania, and the Veterans Administration (VA). The New York City initiative addresses myths vs facts about benzodiazepine and insomnia medications, first-line therapy for anxiety and insomnia, 4 judicious prescribing steps that highlight lowest effective doses for the shortest duration, benzodiazepine treatments, interactions, and pharmacokinetics, use of state Prescription Monitoring Programs (PMP), use of benzodiazepines in special populations (elderly, pregnancy), benzodiazepine physical dependence and withdrawal, substance abuse disorder, discontinuing benzodiazepine therapy and need to avoid long-term (> 4 week) daily or near daily benzodiazepine use. Pennsylvania prescribing guidelines focus on acute treatment of anxiety and insomnia and summarize both conditions and their management. They provide guidelines of what prescribers should do before therapy is started, at initiation, and with other conditions/medications or history of substance abuse, or in the elderly. Written prescriber-patient benzodiazepine agreements, review of PMPs, comparative benzodiazepine kinetics and dosing, as well as benzodiazepine dose reduction and prescribing tools are also addressed. The Veterans Administration program is most comprehensive, addressing overall benzodiazepine use in the United States and within the Veterans Administration, including overdose and fatality statistics and long-term effects of benzodiazepines on cognitive function. For the VA highlights the role of benzodiazepine is short-term therapy. The VA provides an overview of treating anxiety and insomnia and addresses patient populations in which benzodiazepines should be avoided. The VA discusses risk vs benefit in detail for patients taking benzodiazepines with opioids, the elderly, and patients with dementia, post-traumatic stress disorder, or chronic respiratory disease. The VA urges decreasing long-term use and provides discontinuation and taper strategies to achieve this goal. Besides the comprehensive document, the VA also provides a patient info-graphic handout and a 1-page prescriber handout focused on benzodiazepine dosage equivalents, discontinuation, and benzodiazepine taper schedules. As DUR Board members consider benzodiazepine edits, elements for benzodiazepine-related prescriber education should be determined.

State of Illinois Opioid Action Plan. Christina Petrykiw, PharmD noted that a link to the Action Plan is available. Tim Lehan, BSPharm, made a motion to post a link to the Action Plan on the DUR Board education materials Web page, which the DUR Board members unanimously approved. Dr. Goyal clarified that the Action Plan's goal is to decrease opioid-related deaths from the number projected in 3 years. Currently there has been a 50% yearly increase in opioid-related deaths.

Future agenda items.
Dr. Nagelli asked DUR Board members for additional medication use issues HFS should be evaluating, besides those recommended during discussions at this meeting. She requested an update from HFS on the potential effect of a single Preferred Drug List for fee-for-service and managed care pharmacy participants in Illinois for a future agenda. The DUR Board members may forward additional issues they identify to Christina Petrykiw, PharmD.

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

Adjournment. Dr. Nagelli adjourned the DUR Board meeting at 10:35 am.

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

Approved 11/15/2017 by the Illinois Drug Utilization Review Board.