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Drug Utilization Review Board
Meeting Summary

Wednesday, February 17, 2016

The Drug Utilization Review (DUR) Board met on Wednesday, February 17, 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: Tracy Jordan, PharmD; Tim Lehan, BSPharm; Anitha Nagelli, PharmD, M.Ed; Vice-chairperson; John E. Tulley, MD.

Illinois Department of Healthcare and Family Services (HFS) Representatives: Stewart Chung, PharmD, Prior Authorization, University of Illinois at Chicago (UIC); Donna Clay BSPharm, 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; Lori Uildriks, PharmD, BCPS, CGP, UIC.

Interested parties: Chris Gillette, Pfizer; Marcia Luckett, Genentech, Inc.; Judy Kelloway, PharmD; Judy King, MD; Roberta Neuwirth, GSK; Ashley Polce, Abbvie; Corinne Puchala, PharmD candidate, UIC College of Pharmacy; David Puteco, ViiV Healthcare; Jeff Samels, Vertex; David Skibicki, Pfizer; Gary Thurnauer, Pfizer.

*Attendance via teleconference

Call to Order. Anitha Nagelli, PharmD, called the meeting to order on February 17, 2016 at 8:34 am.

Agenda, conflict of interest review, and approval of September 23, 2015 meeting minutes. Illinois DUR Board members had no changes to the February 17, 2016 meeting agenda or the September 23, 2015 minutes. John Tulley, MD, made a motion and the DUR Board unanimously approved the September 23, 2015 minutes. Anitha Nagelli, PharmD, 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.

DUR Board membership. Mary Lynn Moody, BSPharm, welcomed new DUR Board members, Tracy Jordan, PharmD and Tim Lehan, BSPharm. Anitha Nagelli, PharmD, thanked Lori Wilken, PharmD for her years of service and contributions to the DUR Board.

DUR Board meeting schedule for 2016. Christina Petrykiw, PharmD, reviewed the DUR Board meeting schedule for 2016. John Tulley, MD made a motion, seconded by Tim Lehan, BSPharm, and the DUR Board unanimously approved the meeting schedule for 2016. The meeting schedule is posted on the Illinois DUR Board Webpage at http://www.illinois.gov/hfs/About/BoardsandCommisions/DUR.

Department of Healthcare and Family Services, Bureau of Professional and Ancillary Health Services report. Patty Steward, BSPharm, informed DUR Board members that effective October 1, 2015, HFS transitioned from the International Classification of Disease, 9th edition (ICD-9) to ICD-10 for classification of diseases, injuries, and causes of death. All claims now submitted should include the ICD-10 code. Patty Steward, BSPharm, noted that BPAS has been working on implementation of Illinois House Bill 001 (HB1 or Lali's Law), which signed into law coverage without restrictions for FDA-approved medication-assisted treatment (MAT) for substance use disorders. Substance use disorders may include alcohol, prescription opiate, or heroin abuse. This legislation removed prior

authorization requirements and lifetime limits on MAT. Medication-assisted treatments may include naltrexone, buprenorphine, methadone, disulfiram, and acamprosate. The MAT therapies for opioid use disorder are dispensed by Substance Abuse and Mental Health Services Administration (SAMHSA)-certified opioid treatment programs. The MAT therapies have been available without restriction for substance use disorder effective October 21, 2015. Billing will be adjusted retroactively to September 9, 2015. The HB1 legislation also made the naloxone antidote for treatment of opioid overdose more available. Before naloxone is readily available, prescribers and dispensing pharmacists must be trained. The Department of Public Health is responsible for the education and training. Naloxone will continue to require prior authorization, until provider education and training are completed.

Prospective Drug Review

Drugs & Therapeutics Committee – 2015. Christina Petrykiw, PharmD, notified DUR Board members about the 27 medications reviewed by the Drug & Therapeutics Committee in 2015 at their quarterly meetings. All of these medications require prior authorization, unless impacted by HB1 legislation. The prior authorization criteria are developed by Prior Authorization staff in consultation with the Drug Information Group at UIC College of Pharmacy and the Prior Authorization Medical Directors. The criteria may be presented to the DUR Board throughout the year. Mary Lynn Moody, BSPharm, noted that in 2015 the Food and Drug Administration (FDA) approved 45 new medicines, almost an all-time record. Many new medications target orphan diseases, defined as conditions that affect 200,000 or fewer persons. In total, these new medications have an annual drug cost of 25 million in addition to monitoring costs. Many of the new medications incorporate novel genetic testing to identify the best candidates for optimal outcomes.

Cystic Fibrosis. Christina Petrykiw, PharmD, provided a brief overview of cystic fibrosis, treatments for cystic fibrosis, and goals of therapy. The unique characteristics of lumacaftor-ivacaftor (Orkambi), which was approved by the FDA on July 2, 2015, were reviewed. Lori Uildriks, PharmD, provided an overview of initial and renewal prior authorization criteria for Orkambi. The criteria are posted on the Prior Authorization Web page at http://www.illinois.gov/hfs/MedicalProviders/Pharmacy/Pages/CriteriaandForms.aspx. At least 40 requests have been received, with 40% approved. The majority of denials have been for insurance eligibility reasons (third party payer or managed care participant). John Tulley, MD, asked what goals of therapy are considered for Orkambi and why fewer renewals are approved than initial approvals. Lori Uildricks, PharmD, noted that improved quality of life, improved forced expiratory volume (FEV_1), and weight gain are among the therapeutic benefits. To date there are fewer renewals approved either because the patient has transitioned to managed care or the participant is still in the first 3 months of the initial approval. Arvin Goyal, MD, noted that Orkambi is indicated for children 12 years of age and older. Anitha Nagelli, PharmD, asked if pediatric participants were among the initial denials and whether staff follow-up on Orkambi denials. Lori Uildricks, PharmD noted that some of the denials were younger pediatric participants. Staff do not routinely follow-up on participants for whom a medication is denied.

Heart failure. Christina Petrykiw, PharmD, provided a clinical review of heart failure and its treatment based on disease stage. Information about the combination of sacubitril and valsartan (Entresto), approved by the FDA on July 7, 2015, was provided. The PARADIGM-HF trial comparing Entresto and enalapril was stopped early due to therapeutic benefits noted. Potential concerns with this neprilysin inhibitor include beta-amyloid plaque accumulation because neprilysin is a beta amyloid-degrading enzyme in the brain. The FDA is requiring post-marketing studies to evaluate impact on cognitive function and also to determine incidence of angioedema in African American patients. Entresto's current place in therapy is in conjunction with other heart failure therapies to decrease the risk of cardiovascular death and heart failure-related hospitalizations. It would replace an ACE-inhibitor or angiotensin receptor blocker. Stewart Chung, PharmD, reviewed initial and renewal prior authorization criteria for Entresto. To date, 14 requests have been received. Approvals for different strengths have been in the same patient. Denials have been due to insurance eligibility issues and lack of adherence with current heart failure therapies or subtherapeutic doses of current therapies. Mary Lynn Moody, BSPharm, noted that valsartan has increased bioavailability compared with the comparator drug enalapril in the PARADIGM-HF trial and that results may have been different if Entresto was compared with valsartan instead. John Tulley, MD, noted that if reasonable treatment doses are taken, exacerbation should not occur. Dose escalation may not be necessary. Arvin Goyal, MD, recommended removing cardiology fellows from the criteria and only requiring the cardiologist since the fellows are working under the cardiologist. John Tulley, MD, noted that even if the cardiology fellow writes the prescription, it must be co-signed by the cardiologist. John Tulley, MD, made a motion, seconded by Tim Lehan, BSPharm, and the DUR Board unanimously approved the criteria with the suggested modification.

Hereditary angioedema. Christina Petrykiw, PharmD, provided an overview of the orphan disease state, hereditary angioedema, and the treatments available for prevention or treatment of angioedema attacks. Currently five medicines exist for the management of hereditary angioedema. The prior authorization initial and renewal criteria for all agents as well as specific Cinryze criteria were reviewed. Allergists, immunologists, or hematologists must be involved in the treatment of the patient and clinical documentation of antigenic and functional levels are necessary. John Tulley, MD, noted that many of these medications are provided in the physician office. Donna Clay, BSPharm, informed the DUR Board members that Cinryze is administered at home every 3 days and that Firazyr is a subcutaneous injection that is provided for the patient for home therapy as well. Most patients will have a combination of physician office or home therapy and may also go to the Emergency Room for the medications. To date, requests were received for 9 patients. Follow-up is routine to ensure that there is no gap with prior authorization so that patients can get therapy when needed. If patients do not have many episodes, prior authorization duration may be extended. Tim Lehan, BSPharm, made a motion, seconded by John Tulley, MD, and the criteria were unanimously approved.

Retrospective Drug Utilization Review

Tramadol use in children. Christina Petrykiw, PharmD, addressed the new potential safety issues with tramadol use in children. Tramadol is available as a single ingredient product in several different oral dosage forms and in combination with acetaminophen. It is indicated for the treatment of moderate to moderately severe pain in adults, but has been used off-label in children. The FDA is evaluating safety of use in children because cases have been reported of children receiving 1 dose of liquid tramadol after tonsillectomy and experiencing difficult or slow breathing. Management has included hospitalization. Children may be ultra-rapid metabolizers of tramadol, which can result in more active metabolite, O-desmethyl-tramadol, in the body. The ultra-rapid metabolizers have genetic variations that result in faster and more complete metabolism to the active tramadol form. The FDA recommends parents and caregivers watch for changes in breathing, confusion, or unusual sleepiness in children receiving tramadol. If symptoms occur, the tramadol should be stopped and the child taken to the Emergency Room or 911 contacted. Participants currently taking tramadol should discuss use with their physician. Side effects should be reported to the Medwatch program. For future opioid medications used in children, the FDA just announced a new requirement for the Pediatric Advisory Committee to make recommendations before new labeling is approved for children. Presently in HFS, the tramadol 50-mg dosage form is preferred and all other dosage forms and strengths require prior authorization. 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. John Tulley, MD, noted it would be good to have comments from pediatricians regarding tramadol usage in children. Arvin Goyal, MD, noted other alternatives for children include non-steroidal anti-inflammatory drugs and liquid formulations of narcotics. Physicians should not escalate therapy, unless needed. The DUR Board members thought limiting usage to age 18 years and older may be appropriate due to this being an off-label indication. It is not safer than other medications. The DUR Board members tabled making a decision until pediatric input is received.

Pain management. Christina Petrykiw, PharmD, reviewed data about the Pain Management Program. Despite implementation of monthly quantity limits, prior authorization for select dosage forms, narcotic edits for high utilization and lock-in programs to one prescriber or pharmacy, significant narcotic overutilization was still evident. The Pain Management Program aims to decrease inappropriate prescribing of narcotic analgesics for chronic, non-cancer pain. Providers of patients who have been using narcotics chronically for whom a narcotic request is received, fill out a letter of medical necessity for long-term opioid use in pain and submit a patient-provider opioid agreement. Providers and staff check the Illinois Prescription Monitoring Program to verify narcotic fill histories. In total, from fiscal year 2013 to the present over 40,000 initial letters of medical necessity were sent and 37% of the forms were returned. At least 69% of requests were approved. Over 5,300 renewal letters of medical necessity were sent with 84% returned. At least 59% of renewal requests were approved. The pain program helps focus attention on prescribing of narcotic analgesics, facilitates patient-provider opioid agreements, facilitates targeted prescriber intervention to improve pain management, and impacts utilization of narcotics. The DUR Board members discussed requesting letters of medical necessity after 1 month of continuous use, rather than the current 3 months, since dependence can occur within a month of therapy. Arvin Goyal, MD, noted that there is a difference in narcotic need acutely versus chronically, and 28 days would be maximal for acute use. Approvals after 1 month should not be approved if the patient is not terminal. The longer use facilitates dependence, potentially causes addiction, and may facilitate diversion. Requiring urine drug testing may be an option. Anitha Nagelli, PharmD, noted that sending out the letter earlier could help clarify which patients require chronic therapy long-term sooner and could be beneficial.

Currently letters of medical necessity are requested for participants for whom an adjudication request for chronic narcotic therapy is received. The DUR Board members discussed using claims data to identify other HFS participants who fill narcotics regularly, but for whom an adjudication request is not received. Mary Lynn Moody, BSPharm, noted that pharmacies may have patients pay cash or help ensure narcotics are among the first 4 prescriptions filled, so that a prior authorization requirement is not triggered. Patients end up using narcotics long-term and become dependent. Linda Schuh, BSPharm, noted that currently a narcotic edit is in place for 24,000 patients. One of the criteria for a narcotic edit is more than five opioid prescriptions filled in the past year. If the requirement for the pain program changes to all patients who fill for more than 30 days, then prior authorization will be required. John Tulley, MD, voiced concern about sending out the letter after 1 month because this may be burdensome for providers and the intent is not to stop medication in patients who need longer therapy, for example after surgery. It was noted that 1 month would allow a check of who needs longer therapy and would let the surgeon who prescribed the narcotic re-evaluate whether dose adjustments were warranted since now the patient is past the acute surgical period. Arvin Goyal, MD, noted that 30-day approvals were reasonable and would facilitate provider education about appropriate narcotic therapy sooner. This is even more significant now with the level of narcotic overdoses that are occurring. State medical association audits have revealed that often other providers write the narcotic renewal to the same directions as the surgeon's post-surgical treatment and the surgeon is not aware the patient is continuing the therapy longer or at higher doses than originally intended. Shorter approvals may help decrease the psychological dependence on opioids and constraint diversion. The DUR Board members also discussed impact of the pain program and patient-provider opioid agreements on narcotic utilization and whether a shift to cash payment was occurring. Mechanisms to require providers checking the Illinois Prescription Monitoring Program (ILPMP) database were discussed. Currently one patient at a time can be assessed, but populations cannot be easily checked. Patty Steward, BSPharm, noted that HFS has reached out via the Office of the Inspector General to create data-sharing agreements with ILPMP to facilitate addressing population narcotic use. Claims data may need to be assessed to determine if patients in the Pain Management Program are using other treatments for pain and decreasing reliance on narcotics, particularly in conditions for which narcotics are not overly effective, such as fibromyagia. John Tulley, MD, noted that recently published data showed that patients who overdosed received prescriptions for the same narcotics soon after discharge for overdose management. Providers may not be aware of Emergency Room visits or hospitalizations for overdoses. Anitha Nagelli, PharmD, reiterated that a 30-day treatment without prior authorization was reasonable for the controlled substances. This would limit manipulation of the Four Prescription Policy. For renewals, patient-provider contracts should be in place and prescribers should provide justification for long-term opioid therapy. Staff should verify diagnoses via medical claims review.

Future agenda items. Anitha Nagelli, PharmD, noted that future items should include resolution of the age edit for children for tramadol, Pain Management Program criteria update, and usage of narcotics in disease states where they may not be overly effective, for example fibromyalgia. If DUR Board members identify other issues that should be evaluated, they should send them to Christina Petrykiw, PharmD.

Public comments. Judy King, MD, suggested that generic names of medications on Drug & Therapeutics Committee agendas and meeting results be posted along with the brand names. Dr. King also requested that meeting agendas for the Drug Utilization Review Board meetings be posted sooner than 48 hours prior to the meeting and that posting of meeting presentations would be useful. She voiced concern that some prior authorization criteria require the participant to see a specialist. Access to specialists is often an issue for the HFS population. It is also concerning that limits are placed on pain medications to decrease substance abuse, but the medicines may really be needed to treat pain. Dr. King also noted that the HFS Medical Advisory Committee Public Education and Quality Care Subcommittee meetings allow participation via teleconference once participants register. Dr. King suggested this would be good to consider for the Drug Utilization Review Board meetings.

Adjournment. Anitha Nagelli, PharmD, adjourned the DUR Board meeting at 10:17 am.

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

Approved May 18, 2016 by the Illinois Drug Utilization Review Board.