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Drug Utilization Review Board

Meeting Summary

Wednesday, January 15, 2014

The Drug Utilization Review (DUR) Board met on Wednesday, January 15, 2014, at 8:30 a.m. in the B-16 Conference Room, University of Illinois at Chicago College of Pharmacy, 833 S. Wood Street, Chicago, Illinois.

DUR Board members in attendance: Rachel Caskey, MD, Chairperson; Anitha Nagelli, PharmD, M.Ed, Vice-chairperson; John E. Tulley, MD; Lori Wilken, PharmD, AE-C.

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 Pharmacy Services (BPS); Mark Huston*, HFS BPS; Mary Lynn Moody, BSPharm, UIC; Christina Petrykiw, PharmD, CDE, UIC; Linda Schuh*, BSPharm, HFS BPS; Patricia Steward*, BSPharm, HFS BPS.

Interested parties: Darren Brumfield, Daiichi Sankyo; Tom Erikson, BMS; Kevin Hamer, Impax Labs; Judy King, MD; Aimee Kulusic, AbbVie; Mike Krug, Sunovion; Michael Lafond, AbbVie; Deborah Mance, Hyperion; Jim McNamara, ViiV Healthcare; Sam Roe, Chicago Tribune; Gary Thurnauer, Pfizer; Lisa Willshaw, MedImmune.

*Attendance via teleconference

Call to Order. Rachel Caskey, MD, called the meeting to order on January 15, 2014 at 8:30 am.

Agenda, conflict of interest review, and approval of October 23, 2013 meeting minutes. Rachel Caskey, MD, called for a vote to approve the October 23, 2013 minutes after members noted no changes to the minutes or the meeting agenda. John Tulley, MD, made a motion, seconded by Lori Wilken, PharmD, and the DUR Board unanimously approved the October 23, 2013 minutes. Rachel Caskey, MD, reminded DUR Board members to recuse themselves from discussion if they have a conflict of interest and to provide staff with an updated Conflict of Interest form when conflicts arise. Christina Petrykiw, PharmD, provided a copy of the 2014 meeting schedule for the DUR Board that was approved at the October 23, 2013 meeting. The schedule is posted on the DUR Board Website.

Department of Healthcare and Family Services, Bureau of Pharmacy Services report. Mark Huston, HFS BPS, informed DUR Board members that at least 50,000 new clients have signed up for Medicaid in Illinois as part of Affordable Care Act initiatives. The Bureau of Pharmacy Services met with physicians, representatives of the Illinois Psychiatric Society, and the Division of Alcoholism and Substance Abuse (DASA) to discuss prior authorization renewal criteria for Suboxone. In the next few weeks a conference call will be held regarding implementation of the Four Prescription Policy in children. If interested in attending the conference call, send an email to Mark Huston, HFS BPS, or Mary Lynn Moody, BSPharm. Rachel Caskey, MD, asked about the number of new pediatric enrollees. Mark Huston, HFS BPS, will provide the DUR Board demographic information for new enrollees once available.

Safety-related Issues.

Acetaminophen. Christina Petrykiw, PharmD, reviewed information related to acetaminophen safety. At least 28 billion doses of acetaminophen are purchased by consumers in the United States. Approximately a third each are single-ingredient over-the-counter (OTC), combination-ingredient OTC, and prescription combination narcotic products. Over 209,000 prescription claims have been paid by Illinois Medicaid in fiscal year 2013 for combination narcotic products containing more than 325 mg of acetaminophen per oral dosage unit. The maximum daily

acetaminophen dose is 4 grams. At doses over 4 grams per day, abnormal liver function tests, acute hepatic failure that may require a liver transplant, and potentially death, ensue. There is little difference between the maximum therapeutic dose and a toxic dose of acetaminophen. Toxic effects occur with lower doses in patients who have underlying hepatic disease or consume alcohol. Accidental or intentional acetaminophen overdose resulted in over 56,000 Emergency Room visits, 26,000 hospitalizations, and at least 458 deaths from 1990 to1998. Acetaminophen is the leading cause of acute liver failure, with the majority of injury in pediatric patients due to medication errors. Concomitant use of multiple acetaminophen-containing products and lack of ingredient awareness have contributed to toxicity. The Food and Drug Administration (FDA) has taken several actions, including addition of warnings about the dangers of concomitant alcohol use to OTC product labels. Public Advisory Meetings addressed appropriate management of acetaminophen therapy and expanding warnings about hepatic toxicity. Public education campaigns targeted safe use of acetaminophen/non-steroidal anti-inflammatory agents and not using several acetaminophen-containing products concomitantly. Voluntary changes to prescription labeling, such as eliminating acetaminophen abbreviations [APAP], were requested. In 2011 weight-based dosing for children 2 to 12 years of age was added to age-based dosing. A 10-15 mg/kg dose was recommended for children 6 to 12 months of age. A new liquid concentration for neonates (160 mg/5mL) was released in 2011. Based on concerns of liver toxicity with high doses of acetaminophen, the FDA requested manufacturers to discontinue making products with acetaminophen doses greater than 325 mg per capsule/tab in 2011. The requirement became effective January 1, 2014. The prescription product attention is a continuation of efforts made to reduce risk that started with OTC products. In 2013 the FDA also put out warnings about rare, serious skin reactions (Stevens-Johnson Syndrome, toxic epidermal necrolysis, and acute generalized exanthamous pustulosis) that have occurred in patients taking acetaminophen. Acetaminophen-containing prescription products that will remain on the market were reviewed. Appropriate dosing of acetaminophen-containing products in adults and children was also addressed. The DUR Board members discussed appropriate age limits, daily doses, and maximum quantities per fill and per month for prescription combination narcotic products containing acetaminophen. Lori Wilken, PharmD, provided input from pediatric specialty pharmacists at University of Illinois Medical Center who recommended using weight-based dosing and starting pediatric dosing of acetaminophen with hydrocodone products at 30 kg. Mary Lynn Moody, BSPharm, noted that current pharmacy and Medicaid computer systems do not capture weight as a field, but age can be utilized. Christina Petrykiw, PharmD, will inform members the approximate ages a 30-kg weight will reflect. Lori Wilken, PharmD, made a motion to approve Illinois Medicaid changes for acetaminophen-containing products that was seconded by John Tulley, MD. The DUR Board voted unanimously to

- Make oral combination prescription products that contain more than 325 mg of acetaminophen per dosage unit non-preferred, consistent with FDA actions;
- Adjust age limits and maximum quantities as appropriate for ingredients;
- Limit liquid combination products to a maximum of 473 mL, since the majority of the time it is anticipated that patients will convert to tablets or capsules after a short time period.

Additional product would require prior authorization, allowing for provider education regarding acetaminophen dosing safety. Adjusting limits should help decrease potential for diversion of products that contain narcotics.

Simvastatin 80 mg. Mary Lynn Moody, BSPharm, reviewed utilization of simvastatin 80 mg. The Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine (SEARCH trial) demonstrated minor decreases in LDL-cholesterol with increased incidence of myopathy and rhabdomyolysis in patients receiving simvastatin 80 mg compared to patients receiving simvastatin 20 mg. Due to increased potential for muscle damage with simvastatin 80 mg, particularly in the first year of therapy, the FDA issued warnings about appropriate simvastatin use in 2011. If LDL-cholesterol goals cannot be achieved with simvastatin 40 mg, the patient should be switched to a more potent statin, rather than increasing the simvastatin dose to 80 mg. Simvastatin 80 mg, atorvastatin 20 mg, and rosuvastatin 10 mg provide comparable LDL-cholesterol lowering. Simvastatin 80 mg became non-preferred for Illinois Medicaid on May 23, 2013. Between May and December 2013 at least 331 authorization requests were received (194 prior authorization and 137 Four Prescription Policy). Fifty-three requests were approved, while the rest were denied due to insufficient justification, availability of equally effective alternate therapy, or discontinuation after physician review. The Medication Review and Academic Detailing staff identified and evaluated patients receiving simvastatin 80 mg for less than one year. At least 537 providers were contacted. Medication changes included switching to a lower simvastatin dose (n=43), pravastatin therapy (n=14), lovastatin therapy (n=9) or atorvastatin therapy (n=177). New insurance coverage was present in 58 patients and 148 patients had stopped statin therapy, while 88 patients continued taking simvastatin 80 mg. Provider outreach revealed lack of

awareness of SEARCH Trial results, FDA warnings, available preferred statin alternatives to simvastatin, statin potencies for conversion to a new statin, and patient noncompliance with medication fills. Simvastatin 80 mg usage decreased by approximately 34% after institution of non-preferred status and an additional 56% after provider outreach. John Tulley, MD, made a motion, seconded by Anitha Nagalli, PharmD, to maintain non-preferred status for simvastatin 80 mg, continue provider outreach, and post educational material about appropriate simvastatin use on the DUR Website. The DUR Board members unanimously approved these initiatives. John Tulley, MD, noted that patients taking calcium channel blockers should be limited to appropriate statin doses. An edit is in place to prevent concomitant use of simvastatin and gemfibrozil, while provider outreach addresses concomitant therapy with calcium channel blockers. Contribution of auto-refill practices to inappropriate therapy has decreased after Medicaid stopped reimbursing for auto-refilled prescriptions. Members of the DUR Board felt similar reimbursement practices should be adopted by other insurers or auto-refill should be mandated out of existence. Federal lawsuits regarding auto-refill practices are pending.

Drug Utilization Review.

Utilization of benzodiazepines. Christina Petrykiw, PharmD, reviewed benzodiazepine usage. Benzodiazepines are controlled substances that carry the potential for physical and psychological dependence. Withdrawal symptoms are possible with habitual use beyond 2 weeks and with higher doses. Review of psychiatric cases at the last DUR Board meeting revealed benzodiazepine overutilization. Additionally, as with all controlled substances, there is risk of misuse and diversion. Available benzodiazepine dosage forms and their FDA-approved and off-label indications were reviewed. Regardless of indication, daily frequency of administration is four times daily for all benzodiazepines, except clonazepam, which is usually dosed three times daily. Approximately 170,000 Medicaid clients in Illinois have filled benzodiazepine prescriptions annually from 2010 to 2012. In 2013, usage dropped to about 80,000 patients in part due to shift of payment coverage to managed care or to Medicare Part D (dual eligible patients). Breakdown of anti-anxiety medication usage in Illinois Medicaid clients is as follows: alprazolam (39%), clonazepam (24%), lorazepam (20%), diazepam (10%), buspirone (7%), chlordiazepoxide (0.56%), clorazepate (0.46%), and oxazapam (0.06%). A Government Accounting Office (GAO) prescription claims review in 5 states, including Illinois, revealed fraud and abuse in Medicaid for benzodiazepines and other controlled substances. The need for preventive controls, detection and monitoring for misuse and fraud, and investigations as well as prosecutions was noted. The GAO noted that one mechanism available to states to identify and prevent doctor shopping or substance abuse includes use of Drug Utilization Review with prospective screening, edits, prior authorization processes, and restricted recipient programs. Specific mechanisms available include preferred drug status, requiring prior authorization, daily and monthly quantity limits, age restriction, duration of therapy and indication-based limits. Current Illinois requirements for individual benzodiazepines were reviewed and compared to 13 states with large Medicaid populations as well as to 5 Illinois-neighboring states. Although generic versions of all benzodiazepines are Medicaid preferred for most states, a few states exclude oxazapam. Texas requires prior authorization for all benzodiazepines, while Pennsylvania and Georgia require prior authorization after 2 or 3 fills, respectively. Other states require prior authorization for select dosage forms of benzodiazepines. Illinois provides a daily quantity limit based on total milligrams, while other states note maximum number of tablets or milliliters allowed per day. Some states employ maximum monthly quantities of 1-month supply or 90 tablets for immediate-release alprazolam, clorazepate, or clonazepam, while the majority of states reviewed employ a 120-tablet monthly quantity limit for most immediate-release formulations. Illinois has a duplicate therapy edit in place that allows only one agent in the benzodiazepine drug class for treating anxiety within a 30-day period and a monthly maximum of 300 tablets with fewer tablets allowed per fill. An indication check is applied for clonazepam, eliminating medication review if there is HFS documented seizure indication for a patient. The Four Prescription Policy addresses appropriateness of benzodiazepine therapy. Since December 2012, over 4,843 letters have been faxed to providers regarding Four Prescription Policy overrides for benzodiazepines. Duration of approval is dependent on current length of therapy, diagnosis, concomitant disease states, and presence of appropriate non-benzodiazepine therapy for anxiety consistent with evidence-based published guidelines. Anitha Nagelli, PharmD, made a motion to approve, seconded by John Tulley, MD, and the DUR Board unanimously approved the following:

- Continue provider outreach for long-term benzodiazepine therapy without SSRI/SNRI therapy for anxiety;
- Maintain benzodiazepine duplicate therapy edits and the seizure indication check for clonazepam;
- Create provider educational materials regarding appropriate benzodiazepine use and tapering strategies; and
- Adjust monthly quantity limits to 120 tablets for all benzodiazepines, except clonazepam, which would have a maximum monthly quantity of 90 tablets.

Educational initiatives.

MEDI training. Mary Lynn Moody, BSPharm, provided an update regarding ongoing education efforts. Initial training targeted sites with high Medicaid populations. Onsite training was completed in Springfield, Champaign, Rockford, and Chicago. Telephone- and Web-based training is ongoing. Providers like MEDI access, particularly the ability to see approval/denial information for submitted requests. Sites interested in training for clinic staff should contact Mary Lynn Moody, BSPharm. Dr. Tulley, MD, will help set up training for medical clinic staff at University of Illinois Medical Center. Training may be worthwhile to include in new medical resident orientation.

Education materials for DUR Website. Christina Petrykiw, PharmD, reviewed the education materials proposed by the DUR Board for posting on the DUR Web page at the October 2013 meeting. The *Resources for Managing Vitamin D Therapy* educational item includes links to guidelines as well as algorithms to assess fall or fracture risk. Frailty risk assessments were not readily linkable, but some of the resources in the link for the Centers for Disease Control and Prevention STEADI tool kit address this topic. The *Opioid Pain Management – Provider Continuing Education Resources* educational item provides links to FDA–required Risk Evaluation and Mitigation Strategies (REMS) for opioids as well as select pain management continuing education activities and certification programs for health care providers. Anitha Nagelli, PharmD, made a motion, seconded by Lori Wilkens, PharmD, and the DUR Board members unanimously approved the educational items for posting on the DUR Board Website.

Public comments

Judy King, MD, asked if Medicaid is following Cook County's CountyCare guidelines. Mary Lynn Moody, BSPharm, noted Medicaid does not follow the same guidelines as CountyCare, which started as a demonstration project to expand Medicaid to uninsured adults.

Judy King, MD, commented regarding communication of changes for contraceptive Plan B coverage to providers and Medicaid clients. Dr. King noted that there seems to be confusion regarding coverage of OTC Plan B for women less than 17 years of age. Patricia Steward, HFS BPS, noted that coverage has been in place since August 2013 for younger patients. Patricia Steward, HFS BPS stated that female Medicaid recipients ages 10 to 55 years of age with a medical card can obtain Plan B without a prescription. Judy King, MD, noted that more education is needed for adolescents and their medical and pharmacy providers because lack of knowledge of coverage changes exists. The DUR Board members mentioned that education may be needed for pharmacy technicians, who are often the first person a client talks to in the pharmacy. If technicians see that Plan B is an OTC item, knowing that most OTC items are not covered, they may tell the patient it is not covered without referring the patient to the pharmacist or trying to get a claim processed. Mary Lynn Moody, BSPharm, thanked Dr. King for the education suggestion. Some concerns regarding Plan B expanded use have been raised by cases of patients who fill the product monthly, rather than regular use of traditional oral contraceptives. Provider outreach has resulted in patient education about contraceptive therapy.

Adjournment. John Tulley, MD, made a motion that was seconded by Lori Wilkens, PharmD, to adjourn the meeting. Rachel Caskey, MD, adjourned the DUR Board meeting at 9:54 am.

Minutes prepared by Christina A. Petrykiw, PharmD, CDE.

Approved 4/23/2014 by the Illinois Drug Utilization Review Board.