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Drug Utilization Review Board

Meeting Summary

Wednesday, July 23, 2014

The Drug Utilization Review (DUR) Board met on Wednesday, July 23, 2014, at 8:30 a.m. in Conference Room 270, 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); Arvind K. Goyal*, Medical Director, Medical Programs, HFS; Mary Lynn Moody, BSPharm, UIC; Christina Petrykiw, PharmD, CDE, UIC; Linda Schuh*, BSPharm, HFS BPS; Patricia Steward*, BSPharm, HFS BPS, Jay Tran, PharmD, UIC.

Interested parties: Darren Brumfield, Daiichi Sankyo; John Bullard, Amgen; Tom Erikson, BMS; Mark Davis, Vertex; Palak Desai, Harmony Wellcare; Chris Gillette, Pfizer; Robert Hook, Chiesi; Judy King, MD, Community Mental Health Board of Chicago; Jeff Knappen, Allergan; Mike Krug, Sunovion; Michael Lafond, Abbvie; Terry McCurren, Otsuka; Ashley Polce, Abbvie; Matt Wessels, Walgreens; Lisa Willshaw, MedImmune.

*Attendance via teleconference

Call to Order. Rachel Caskey, MD, called the meeting to order on July 23, 2014 at 8:33 am.

Agenda, conflict of interest review, and approval of April 23, 2014 meeting minutes. Illinois DUR Board members noted no changes to the agenda. Rachel Caskey, MD, called for a vote to approve the April 23, 2014 minutes with the spelling correction of Lori Wilken, PharmD's name at the end of the minutes. John Tulley, MD, made a motion, seconded by Lori Wilken, PharmD, and the DUR Board unanimously approved the April 23, 2014 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.

Department of Healthcare and Family Services, Bureau of Pharmacy Services, report. Mary Lynn Moody, BSPharm, UIC, notified Board members of a legislatively mandated change to the Four Prescription Policy. As of July 1, 2014 atypical and typical antipsychotic agents will be filled without an approval requirement for the Four Prescription Policy. Prior authorization will still be required if a medication is not on the preferred drug list or has an age, quantity, long-term care, or other prior authorization requirement in place. Rachel Caskey, MD asked if there was an update regarding inclusion of pediatric patients into the Four Prescription Policy. Mary Lynn Moody, BSPharm, UIC, noted no update was available at this time.

Prospective Drug Utilization Review.

New edits. Christina Petrykiw, PharmD, CDE informed DUR Board members about two new prospective edits that have been implemented. Effective June 30, 2014, an age edit was implemented for oral viscous lidocaine 2% solution. The product is now restricted for ages 5 to 99 years. The Food and Drug Administration (FDA) requires a boxed warning that this product should not be used to treat teething pain as of June 26, 2014. Excess doses have resulted in cases of seizures, severe brain injury, heart problems, hospitalizations, and death. A review of claims paid for lidocaine noted that 16% of claims had been for children 0 to 5 years of age. Prior authorization is now required for use in children less than 5 years of age. Effective June 17, 2014, a duration-of-therapy edit was implemented for

varenicline (Chantix®). Clinical efficacy trials evaluated 12 weeks of therapy followed by a repeat of 12 weeks of therapy (a total of 6 months). The FDA approves up to 6 months of continuous therapy. Prior authorization will be required to extend therapy beyond 6 months of continuous use. Approximately 2.5% of HFS clients have used the product longer than 6 months in 2014. Lori Wilken, PharmD, mentioned that a 6-month duration was an improvement over the 90-days allowed for nicotine replacement products. John Tulley, MD, noted that many patients may fail their first attempt at tobacco cessation.

Tobacco cessation. Lori Wilken, PharmD provided an overview of the health benefits of tobacco cessation and current clinical management of tobacco cessation. Illinois ranks 23rd nationally for smoking prevalence. Tobacco use usually starts before 18 years of age and successful cessation may take up to 7 attempts. Health care providers effectively ask and advise regarding tobacco use and cessation, and improvement is evident with patient assessment, but more work is needed in assisting with treatment and arranging follow-up for tobacco cessation. Comprehensive tobacco cessation therapy includes behavior modification counseling and pharmacotherapy with bupropion, nicotine replacement via 5 dosage forms three of which are available over-the-counter, and varenicline. Illinois HFS Medicaid covers 90-days of continuous OTC nicotine replacement therapy with a written prescription – a good benefit compared with some private insurers. High cigarette cost has increased use of patient-rolled cigarettes, with resulting higher carbon monoxide and addiction levels that require higher starting doses of cessation therapies. Patients are unaware of the full scope of health effects of tobacco use and tend to be more afraid of the tobacco cessation therapies due advertisement or product warnings. Proposed changes to labeling for OTC nicotine replacement products aim to encourage use and therapy completion. The FDA's black box warnings for bupropion and varenicline highlight high risk for serious mental health events in users, a co-morbid condition in many Medicaid clients. While noting efficacy in patients with cardiovascular disease and COPD, the FDA also warns about small, increased risks of cardiovascular adverse effects in patients with cardiovascular disease who are taking varenicline. Tobacco cessation therapy doubles long-term (> 6 month) quit rates compared with using placebo. Potential barriers related to pharmacotherapy-enabled tobacco cessation may include prior authorization requirements and failure of retail pharmacy staff processing prescriptions for covered OTC products. The small copayments from IL HFS for OTC and prescription tobacco cessation products have not been seen as a barrier by clients motivated to quit. Treatment failure has been associated with fear of using medications, inappropriate dosing and use, and insufficient counseling for behavioral modification of tobacco use triggers. The Affordable Care Act expanded tobacco dependence treatment, requiring coverage of comprehensive treatment without cost-sharing for pregnant women and Medicaid expansion recipients. Pharmacotherapy coverage, but not counseling, is required for all other Medicaid recipients with or without cost-sharing. Gynecologists and obstetricians may not yet be aware of the coverage changes. Patty Steward, HFS BPS, noted that all pregnant patients have coverage for all medications if they are coded as pregnant in the Medicaid database. Cost savings due to smoking cessation for medical and hospitalization costs for cardiovascular disease has been demonstrated in Massachusetts' Medicaid clients. Christina Petrykiw, PharmD overviewed Medicaid coverage and HFS-specific data for tobacco cessation therapy and efforts. As of January 2014, only 2 state Medicaid programs provide comprehensive coverage and Illinois along with 26 other states provide medication coverage. Illinois HFS encourages providers to screen patients for tobacco use, address tobacco cessation, and provide counseling, interventions, and treatment as well as referral to the toll-free Quitline. Providers may use a treatment enrollment form for the Quitline to facilitate initiating patient contact. Effective January 1, 2014 HFS proposed comprehensive coverage for pregnant clients. The expense of counseling coverage will be offset by fewer premature or low weight births, birth defects, and overall future medical healthcare costs. In Illinois, nicotine replacement therapy is covered for clients 12 years of age and older, while varenicline is for clients 18 years of age and older and bupropion has no age restrictions. The 90-day duration of therapy edit has been in place for nicotine patches since 2006 and expanded to other dosage forms in 2010. The 6-month varenicline duration of therapy edit was implemented June 2014. All tobacco cessation products have demonstrated high uptake initially with fewer clients using products through time. Nicotine replacement products are mainly used, followed by varenicline. Differences in usage are notable with timing of FDA product warnings, availability of new products, or product switch to OTC status. Impact of electronic cigarettes on usage of tobacco cessation products is not yet discernable. Edits are in place for duplicate therapy for individual nicotine replacement products in different strengths and for combination use of different nicotine replacement dosage forms and varenicline. Approximately 5% of nicotine replacement and 6% of varenicline prescriptions are being initially denied for duplication in therapy annually. Refill too soon grants authorization for many of these scripts when requested. Approximately 30% of prescriptions were initially denied for exceeding duration of nicotine replacement therapy. Besides encouraging continuous use to facilitate cessation, the edit helped decrease potential selling of product, which was occurring at the time initial edits were implemented. Actual numbers

of tobacco users is difficult to determine because smoking status is not easily captured with insurer forms or databases and in the majority of cases clients are not presenting to see the physician solely for smoking cessation. Provider reimbursement may contribute to the low numbers of client visits billed for tobacco cessation. The DUR Board members discussed extensively what can be done differently and how to balance resources, yet meet this public health need. Tobacco cessation motivation waxes and wanes with life stressors and is not always accomplished in one continuous session. If a nicotine replacement product is being adjudicated for an edit, asking about concurrent or completed tobacco cessation counseling during the prior authorization/refill too soon authorization process may remind providers to address counseling with patients. Currently the prior authorization system cannot edit for a seizure interaction with tobacco cessation products, but the pharmacist filling the prescription should be checking for seizure history and incorporating routine medication counseling. Combination use of nicotine replacement therapy with varenicline has been seen – a practice not supported by tobacco cessation guidelines. It may be difficult for clients to initiate the Quitline telephone counseling. A pilot program for providers to submit a prescription or request for patient counseling was suggested to help initiate a review with the client and facilitate arranging and following through with therapy, including counseling. This would be particularly helpful for providers in areas that do not have readily available tobacco cessation clinics or for those with limited time to address the topic in a medical visit. A physician needs to initiate the process and it must be seamless – when providers note importance patient follow-through improves. Tobacco cessation requires constant provider attention for success. Education and outreach to providers is needed. A Webinar-on-demand with continuing medical education credit for providers regarding current management and coverage of tobacco cessation was suggested as well as information for clients in languages other than English. Community/retail pharmacists should be informed regarding available coverage, potentially at HFS booths at state pharmacy association meetings. Family case managers who work with pregnant clients throughout their pregnancy should be informed of coverage changes. Guest Judy King, MD, asked if there is any data regarding pregnant women quitting without use of medications. Lori Wilken, PharmD, noted that most of the medications for smoking cessation are pregnancy category C (bupropion, varenicline) or D (nicotine replacement products), which physicians are not comfortable prescribing. The majority of pregnant patients quit without the pharmacologic therapies.

Retrospective Drug Utilization Review.

Asthma. Christina Petrykiw, PharmD, overviewed data requested by DUR Board members for pediatric clients with asthma who had more than one emergency room or medical visit during fiscal year 2013 (FY13). Approximately 100,000 pediatric clients have asthma, with about 28% -29% in the 0-4 and the 12-18 year of age groups and about 43% in the 5-11 years of age group. **Medical visits and medication use.** At least 59% of the clients had a medical visit for asthma. Of those who had a medical visit for asthma, 45% of clients had more than 1 medical visit for asthma during FY13. The majority of pediatric clients had 1-3 visits for asthma in FY13. The highest numbers of visits overall were in the teen age group. Of clients who had more than 1 medical visit, 79% had filled a controller medication for asthma (inhaled glucocorticoid, combination long-acting beta adrenergic and glucocorticoid inhaler, leukotriene receptor antagonist, monoclonal antibody to immunoglobin E, long-acting beta-agonist, xanthine, or mast cell stabilizer). Of patients with a primary diagnosis of asthma who had more than one medical visit in FY13, 43% would be defined as having chronic asthma based on having filled 4 or more controller medications during FY13. Twenty-one percent of pediatric clients who had more than one medical visit did not fill a controller medication at all during FY13. Of pediatric clients who had more than one medical visit during FY13, only 77% had filled at least one rescue inhaler (short-acting beta-agonist). Forty-four percent of clients filled 1-2 rescue inhalers (minimum number of inhalers DUR Board members said a patient should have). Approximately 6.4% of clients were filling 7 or more inhalers in the year (excessive number of inhalers DUR Board members felt signaled need for further evaluation of asthma control). Of clients who had more than one medical visit in FY2013, 57% of pediatric clients filled other dosage form of rescue medications (albuterol or levalbuterol inhalation/nebulization solution, albuterol syrup, terbutaline or albuterol tablets). Of clients filling other dosage forms of rescue medications, 68% of clients filled 1-2 times and at least 4% of clients filled seven or more times during FY13. **Emergency room visits and medication use.** At least 13% of pediatric clients with asthma and no COPD went to the Emergency Room (ER) for asthma once. Almost 3% of pediatric clients experienced more than one ER visit during FY13. Of pediatric clients who visited the ER more than once, almost 87% filled a rescue inhaler and almost 9% filled a rescue inhaler 8 or more times in FY13. Almost 78% of clients with asthma filled a non-inhaler rescue medication– almost 4% filling these medications 8 or more times in FY13. Of children with asthma who went to the ER more than once, 81% filled a controller medication and 46% would be deemed to have chronic asthma based on four or more fills of controller medication in FY13 (a HEDIS measure) . Of those who had been to the ER more than once and filled a controller medication, the majority

filled 1-2 different controller medication prescriptions (range 1-8). Leukotriene receptor antagonists (mainly montelukast) accounted for 43% of the controller prescriptions filled, followed closely by first-line steroid inhaler therapy (39%), combination long-acting beta-agonist and glucocorticoid inhalers (17%), and less than 1% of each of the other controller medications. Regardless of which medication was filled, less than 1% of clients filled the controller medication for 12 months. The majority of clients filled their medication 1-2 times in a year. The DUR Board members felt that providers should be informed of the overutilization of rescue inhalers and underutilization of controller medications in their patients. Dr. Caskey requested notifying prescribers whose patients filled rescue inhalers excessively and who had seen the provider more than once, since many times a prescription is written, but the provider is unaware of excessive product use unless the patient returns for a visit. Particular attention should be given to the clients who are excessively filling rescue inhalers and not filling their controller medications. Prescribers of clients who only fill 1-2 controller medications a year, yet have seen the physician more than once should be notified of the non-compliance with medication fills. Dr. Tulley noted that if adults don't think the medication is helping, they don't use it and do not notify him if the medication did not work.

Dr. Goyal thanked staff for an excellent presentation and requested input regarding the potential role of direct observation of therapy (DOT) administration in vulnerable patients. Would DOT via a department of public health nurse or local provider be worthwhile to improve medication compliance for patients whose disease state may be difficult to manage or may be noncompliant? Dr. Caskey noted that this might be interesting, but difficult to accomplish in the real world setting, particularly if there is a large patient population. Dr. Goyal noted that measures such as Emergency Room visits, medical follow-up and preventive measures do not have a direct correlation with outcomes on HEDIS quality measures. Urgent and emergent medical care and referral care improves outcomes.

Educational initiatives.

MEDI training. Mary Lynn Moody, BSPharm, updated members regarding ongoing education efforts, noting that live training of over 100 providers was completed in the Metro East region. At least 30% of users provide prior authorization requests via MEDI currently and provider outreach is ongoing. Electronic submission is faster and more accurate than telephoned or faxed requests. Direct in-office training is provided. Anitha Nagelli, PharmD, asked whether anything can be done about the fast time-out in MEDI.

Education materials for Website. Christina Petrykiw, PharmD summarized the recently published overview of opioid prescribing for chronic pain that noted best guidelines and addressed risk mitigation strategies for opioid prescribing. The HFS Pain Management Program incorporates several of the strategies, including a patient-provider treatment agreement, assessment of medication use, assessment of medication filling via the Illinois Prescription Monitoring Program, and provider review of patient pain management. Anita Nagelli, PharmD made a motion that was seconded by John Tulley, MD and the IL DUR Board members unanimously approved the summary for posting on the Drug Utilization Review Web site at http://www.hfs.illinois.gov/pharmacy/dur.html.

Public comments

Judy King, MD, thanked HFS staff and Board members for addressing tobacco cessation, inquired about posting meeting slides on the DUR Board Website, and asked if meeting notices could be posted sooner than 48 hours prior to the meeting. Judy King, MD, also asked about prior authorization criteria for proton pump inhibitors. Donna Clay, BSPharm, noted criteria prevent unwarranted long-term use and that each request is assessed individually. Unless a diagnosis requires longer duration of therapy, approval is usually granted for 3 months, after which time step-down to H-2 blockers is appropriate. Only select criteria are posted on the Prior Authorization Website because of the difficulty in updating postings with frequent criteria changes. Mary Lynn Moody, BSPharm, noted that the majority of requests for proton pump inhibitors have been for heartburn, which is not very appropriate. Christina Petrykiw, PharmD, stated that for the most part duration of therapy parallels approved package insert information and that life-long therapy is not intended for most indications treated by proton pump inhibitors for safety reasons.

Adjournment. John Tulley, MD made a motion, seconded by Lori Wilken, PharmD, to adjourn the meeting. Rachel Caskey, MD, adjourned the DUR Board meeting at 10:17 am.

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