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Drug Utilization Review Board

Meeting Summary

Wednesday, April 23, 2014

The Drug Utilization Review (DUR) Board met on Wednesday, April 23, 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; John E. Tulley, MD; Lori Wilken, PharmD, AE-C.

Illinois Department of Healthcare and Family Services (HFS) Representatives: Kate Andresen, PharmD, CGP, Prior Authorization, University of Illinois at Chicago (UIC); Donna Clay BSPharm, UIC; Sheri Dolan*, BSPharm, HFS Bureau of Pharmacy Services (BPS); Mary Lynn Moody, BSPharm, UIC; Christina Petrykiw, PharmD, CDE, UIC; Linda Schuh*, BSPharm, HFS BPS; Patricia Steward*, BSPharm, HFS BPS.

Interested parties: Tom Erikson, BMS; Chris Gillette, Pfizer; Kevin Hamer, Impax Labs; Lee Hennigan, GSK; Judy King, MD; Karisa King, Chicago Tribune; Jeff Knappen, Allergan; Mike Krug, Sunovion; Deborah Mance, Hyperion; Terry McCurren, Otsuka; Sam Smothers, MedImmune; Gary Thurnauer, Pfizer; Lisa Willshaw, MedImmune; Marla Wiedenmann, NovoNordisk Biopharm.

*Attendance via teleconference

Call to Order. Rachel Caskey, MD, called the meeting to order on April 23, 2014 at 8:40 am.

Agenda, conflict of interest review, and approval of January 15, 2014 meeting minutes. Rachel Caskey, MD, called for a vote to approve the January 15, 2014 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 January 15, 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, noted that no date has been announced for the inclusion of pediatric patients into the Four Prescription Policy. The Bureau of Pharmacy Services has reached out to providers regarding the ability to dispense a 72-hour supply of medications as an emergency provision in the Pharmacy Handbook. During non-business hours (evenings, weekends, and state holidays) when department staff are not available to accept a prior approval request, the pharmacy can dispense, and the department will pay for, an emergency 72-hour supply of a covered prescription drug to an eligible recipient in an emergency situation. The pharmacy is responsible for following up with a prior approval request for the emergency supply. In order to receive reimbursement for the emergency 72-hour supply, the pharmacy must submit a separate prior approval request that clearly states the request is for the emergency 72-hour supply of the drug. The request must include the quantity dispensed for the 72-hour supply. Since the last meeting the Department of Healthcare and Family Services has also put out informational provider notices regarding the procedure for billing the dispensing fee add-on for birth control methods purchased through the federal 340B Drug Pricing Program and coverage of non-prescription emergency contraceptives (Plan B).

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Prospective Drug Utilization Review.

Suboxone. Christina Petrykiw, PharmD,CDE provided a clinical and regulatory overview of the treatment of opiate and opioid dependence noting that all chronic narcotic use will cause tolerance and dependence, but not everyone will experience addiction. The partial opioid agonist buprenorphine alone or in combination with the opioid antagonist naloxone has expanded treatment options. Donna Clay, BSPharm, provided an overview of assessment for buprenorphine therapy and the HFS prior authorization criteria and forms for buprenorphine. The prior authorization incorporates the Division of Alcoholism and Substance Abuse (DASA) goals for deterring buprenorphine and narcotic misuse and ensuring patients are committed to recovery from narcotic addiction. Prior authorization has always been required for buprenorphine therapy. Desire is to ensure patients adhere to therapy and can restart work and/or school, rather than starting and stopping treatment. Prior authorization facilitates monitoring use. Patient use of alcohol, benzodiazepines, and narcotics concomitantly is assessed. Short-term use of narcotics for dental or surgical procedures may be allowed, but the patient should not be using alcohol and benzodiazepines. Prescribers must have a XDEA number, a treatment plan cosigned with the patient, must participate in behavioral counseling/modification programs, and have evidence of dose tapering. Urine screening results must be provided, with removal from the program if the patient tests negative for buprenorphine. Approval is incremental (2^{nd}, 5^{th}, 8^{th} month of therapy) for a lifetime total of 12 months of therapy. Usage and prior authorization data for buprenorphine sublingual tablets and film were reviewed from 2012 to the present. Changes in usage have reflected availability of new dosage forms (sublingual film) and strengths (4 mg and 12 mg sublingual film). Since institution of the 12-month limit a dramatic drop in unique users has been seen, attributed to those diverting product. Dr. Tulley noted that the street value of Suboxone has increased. The primary denial reason is insufficient medical justification due to missing items, such as urine screen results. Positive feedback about the prior authorization has highlighted improved therapy compliance. Buprenorphine use should help prevent relapse and provide long-term recovery from narcotic addiction. Most patients who relapse have not participated regularly in behavior modification/counseling programs. Many sites conduct the counseling programs on site. Now HFS provides a list of available treatment and counseling facilities to facilitate usage. Dr. Tulley questioned how naloxone allergy is documented, since criteria note that as one requirement for buprenorphine monotherapy. Donna Clay, BSPharm, mentioned that naloxone allergy is not noted frequently and is described by providers as severe headache, which can be a narcotic withdrawal symptom. Dr. Tulley asked about the impact of the 12-month lifetime limit for buprenorphine therapy, since there are proponents for lifelong maintenance therapy. Donna Clay, BSPharm, noted that provider response varies and that buprenorphine treatment is an evolving practice. Renewals are assessed on a case-by-case basis and consideration is given to adherence, meeting criteria, urine screen results, and impact on life activities. The Bureau of Pharmacy Services recommends continuation of prior authorization for buprenorphine monotherapy and combination therapy. An evaluation of whether a shift to self-pay has occurred to avoid compliance with prior authorization criteria may be helpful. The DUR Board unanimously voted to continue prior authorization for buprophenorphine monotherapy and combination therapy.

Retrospective Drug Utilization Review.

Asthma. Christina Petrykiw, PharmD, led a discussion regarding initial findings from the Asthma Retrospective Drug Utilization Review (DUR). An overview of asthma in Illinois was provided addressing incidence, hospitalization and mortality rates. Illinois' Hardin and Pope counties demonstrate highest hospitalization rates. Medicaid and Medicare pay at least 57% of all asthma hospitalizations in Illinois. The DUR Board chose asthma for review because asthma impacts adult and pediatric patients, a high number of unique medications are used to treat asthma, high numbers of HFS clients have asthma, and many medical and prescription claims are paid for HFS clients with asthma. Specific issues addressed include potential overutilization of short-acting beta agonist inhalers along with underutilization of asthma-controller medications, and high emergency room and hospital usage. For fiscal year 2013, approximately 149,000 Medicaid enrollees had an asthma-only diagnosis, with children compromising two-thirds of the total. Discussion centered on the following:

- Analysis by age noted that the greatest number of children with asthma were 5-11 years of age (approximately 45,000), while there were approximately 30,000 each in the 0-4 and 12-18 years of age groups. Approximately 20,000 to 25,000 HFS clients were in the 19-34 and 35-64 years of age groups, respectively. Less than 600 patients were 65 years of age or older.
- Evaluation of prescriptions filled for short-acting beta-agonist rescue inhalers revealed that 64% of all children with an asthma diagnosis and 67% of adults with an asthma diagnosis have filled a prescription for a

rescue inhaler (albuterol, levalbuterol, or pirbuterol). Patients who did not receive any rescue inhaler may have used nebulization therapy to manage an exacerbation. Patients who have an asthma diagnosis, but have not filled a rescue inhaler should be evaluated to determine use of controller and rescue medications available in other dosage forms and asthma-related emergency room visits or hospitalizations.

- Approximately 29% of children and 25% of adults have filled 1 rescue inhaler prescription and 16% of children and 13% of adults have filled 2 rescue inhaler prescriptions. The percent of patients who filled more prescriptions halved with each additional script. Two percent of adults and less than 1 percent of children filled 12 or more inhaler prescriptions annually. Children 5-11 years of age were most the most likely to fill 1-9 prescriptions for rescue inhalers. Adolescents ages 12-18 years of age were more likely to fill 10 or more inhalers annually. Eleven inhalers was the only category where adults were more likely than children to fill a rescue inhaler. The DUR Board members noted that every patient should have 2 rescue inhalers available (one for home use, another at work or school).
- If a rescue inhaler is used twice weekly, 1-2 inhalers that provide 200 actuations each would be used annually. Any patient that has filled more than two prescriptions annually for a rescue inhaler may be targeted for evaluation (19% of children and 29% of adults). The DUR Board members noted that excessive rescue inhaler use was probably 8 or more inhalers annually. Approximately 2,000 children (2%) and 4,000 adults (9%) filled more than 7 rescue inhalers annually. These patients may be signaling ineffective asthma control with frequent asthma exacerbations. These groups should be evaluated for their use of controller medications, emergency room visits, and hospitalizations.
- Evaluation of prescriptions filled for asthma controller medications revealed that only 54% of children with a diagnosis of asthma and 43% of adults with a diagnosis of asthma have filled a controller medication. Children 3 to 11 years of age most commonly filled prescriptions for controller inhalers. Controller medications modulate respiratory physiology to control asthma symptoms and prevent exacerbations. Patients diagnosed with asthma who have not filled a prescription for a controller medication should be evaluated for their use of rescue inhalers, emergency room visits, and hospitalizations.
- National quality measures note filling of 4 or more controller medications annually as persistent asthma, in which case a controller medication should be taken monthly. At least 21% of adults and 23% of children evaluated would be defined as having persistent asthma. Only 5 % of children or adults filled 12 or more controller medications annually. Patients with persistent asthma should be evaluated for their use of rescue and controller medications, emergency room visits, and hospitalizations.
- Location where our asthma patients live should be evaluated to determine where greatest numbers of patients reside to facilitate and maximize targeted educational interventions. Similarly location should be identified for patients who visit the emergency room, are hospitalized or do not see their physician.
- Few patients were hospitalized primarily for asthma (approximately 2% of children and 1% of adults) . More children than adults were hospitalized for asthma. Children through 11 years of age were almost three times as likely as other age groups to be hospitalized. Pediatric and adult patients with asthma who were admitted, were hospitalized 1.1 times. Patients who were hospitalized should be evaluated for their use of rescue and controller medications, medical and emergency room visits.
- Approximately 61% of children and 46% of adults with asthma visited their physician primarily for asthma during fiscal year 2013. Three times more children than adults visited their physician primarily for asthma. Each patient who saw their physician primarily for asthma visited the physician 2-3 times in the year, regardless of patient age. Rachel Caskey, MD, noted that in children, asthma is often addressed as part of the annual wellness visit, which may be why 39% of pediatric patients may not have been seen for asthma primarily. Patients who did and those who did not see their physician for asthma should be evaluated for their use of rescue and controller medications, emergency room visits, and hospitalizations.
- Approximately 14% of children and 13% of adults with asthma visited the emergency room for their asthma. Approximately twice the number of children as adults had emergency room visits for asthma. Children had 1.3 emergency room visits and adults had 1.5 emergency room visits. The majority of emergency room visits were in children 5-11 years of age and secondly in children 0-4 years of age. Similar numbers of adolescents and adults were seen in the emergency room. Adults 65 years of age were the least likely to visit the emergency room for asthma. Patients who visited the emergency room should be evaluated for their use of rescue and controller medications and hospitalizations.
- Patterns in physician seen or pharmacy used should be determined to assess whether provider-specific educational interventions should be conducted.

Asthma, continued. As a next step, the DUR Board members wanted to identify rescue inhaler and controller medication use in pediatric patients with more than one emergency room or physician visit. Additionally pediatric patients that fall into the category of persistent asthma (4 or more controller medications) could be determined.

Educational initiatives.

MEDI training. Mary Lynn Moody, BSPharm, provided an update regarding ongoing education efforts, noting that live training of providers at Ann & Robert H. Lurie Children's Hospital of Chicago has been completed. Low MEDI usage continues, so provider outreach is ongoing. Eventual goal is exclusive MEDI use and no paper prior authorization requests.

Education materials on Website. Mary Lynn Moody, BSPharm reviewed educational materials regarding appropriate statin therapy as well as combination products containing more than 325 mg of acetaminophen prepared per DUR Board member request. Lori Wilken, PharmD made a motion that was seconded by John Tulley, MD to approve the educational item regarding statin therapy. John Tulley, MD made a motion to approve the acetaminophen educational item that was seconded by Lori Wilken, PharmD. Both educational items were unanimously approved and will be posted on the Drug Utilization Review Web site.

Public comments

Judy King, MD, requested a change to the minutes of the April 23, 2014 meeting to clarify her concerns about patients under 17 years of age getting Plan B without a prescription. Judy King, MD, asked about Dr. Goyal's Task Force recommendations related to asthma and emergency room use. Rachel Caskey, MD, will ask Dr. Goyal, since the DUR Board is not familiar with this initiative. Judy King, MD, noted that different copay amounts may impact emergency room use or medication refills and this may be useful to address. Judy King, MD, asked whether the Drug Utilization Review Board will address HFS patients covered under managed care in the future. Christina Petrykiw, PharmD, noted that currently the focus for the DUR Board is the fee-for-service patients and that potential future incorporation of patients under managed care has been discussed. Judy King, MD, suggested assessing patients that are receiving Plan B since coverage changes have occurred. Judy King, MD, asked about Affordable Care Act mandated coverage without cost-sharing for smoking cessation products such as nicotine replacement therapy for pregnant and adult patients.

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

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

Approved 7/23/14 by the Illinois Drug Utilization Review Board.