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Drug Utilization Review Board
Meeting Summary

Wednesday, August 21, 2013

The Drug Utilization Review (DUR) Board met on Wednesday, August 21, 2013, at 8:00 a.m., in the Pharmacy Practice Residents Conference Room, University of Illinois at Chicago College of Pharmacy, 833 S. Wood Street in Chicago.

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

Illinois Department of Healthcare and Family Services (HFS) Representatives: Lisa Arndt*, Bureau Chief, HFS Bureau of Pharmacy Services (BPS); Wendy Blackwood* HFS BPS; Donna Clay BSPharm, Prior Authorization, University of Illinois at Chicago (UIC); Sheri Dolan*, BSPharm, HFS BPS; Arvind K. Goyal*, MD, Medical Director, HFS; Mary Lynn Moody, BSPharm, UIC; Christina Petrykiw, PharmD, CDE, UIC; Christina Quicquaro, PharmD, Prior Authorization, UIC; Linda Schuh*, BSPharm, HFS BPS; Patricia Steward*, BSPharm, HFS BPS; and Lori Uildriks, PharmD, Prior Authorization, UIC .

Interested parties: Darren Brumfield, Daiichi Sankyo; Rudy Christian, Otsuka; Mark Davis, Vertex; Tom Erikson, BMS; Paul Frank, Wellcare Health Plans; Chris Gillette, Pfizer; Mike Lafond, AbbVie; Deborah Mance, Hyperion Therapeutics; Rachel Scif, Otsuka; Sam Smothers, MedImmue; Gary Thurnauer, Pfizer; Sharon Walker, US Bioservices.

*Attendance via teleconference

Call to Order. Rachel Caskey, MD, called the meeting to order April 17, 2013 at 8:05 am.

Agenda and Minutes review.
No changes were suggested to the agenda or meeting summary. John Tulley, MD, made a motion to approve the summary of the April 17, 2013 meeting. Lori Wilken, PharmD, seconded the motion and the summary was unanimously approved. Dr. Caskey 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.

Report from the Department of Healthcare and Family Services (HFS) Bureau of Pharmacy Services.
Lisa Arndt, Bureau Chief BPS, noted the increase in Four Prescription Policy requests via the HFS Medical Electronic Data Interchange (MEDI) system that has resulted from concerted education and outreach efforts with providers, particularly those in physician offices. Medical providers are identified for MEDI outreach efforts as part of prior authorization processes. Dr. Goyal noted that lack of computer access may complicate ability to submit requests via MEDI. Medical society surveys have shown that approximately 40% of Illinois physicians do not use a computer in their private practice. A high percentage of these physicians are in the Chicago area. Since many of these physicians may be close to retirement, they do not see the benefit of increased cost to the practice associated with implementation of electronic initiatives. Mary Lynn Moody, BSPharm, asked Dr. Goyal to forward the surveys to staff. Lisa Arndt, Bureau Chief BPS, mentioned that the Four Prescription Policy is facilitating the required annual comprehensive review of the patient and their medications, a definite benefit. As of July 22, 2013, pharmacists may submit Four Prescription Policy prior authorization requests via MEDI. Pharmacies serving long-term care facilities have been submitting requests since February 4, 2013. At least 25% of all requests currently received are from pharmacies. Mary Lynn Moody, BSPharm, informed members that additional educational efforts with pharmacists will include presentations and MEDI training at the upcoming state pharmacy society meetings (Illinois Pharmacists Association Annual Conference September 26-29, 2013 and Illinois Council of Health-System Pharmacists Annual Meeting September 19-21, 2013). Providers can now check the status of

their request electronically via MEDI or can submit an electronic status request via the Internet. Status updates are provided by phone or via email. Dr. Caskey suggested adding a footer regarding MEDI availability and training at the bottom of all update communications as part of the educational effort.

FFY 2012 Medicaid Drug Utilization Review Annual Report.
Christina Petrykiw, PharmD, informed Board members that the FFY 2012 Medicaid Drug Utilization Review Annial Report that reflects the time period of October 1, 2011 through September 30, 2012 was submitted on time on 6/28/13. The report is now available on the federal Medicaid Web page.

Prospective Drug Utilization Review

Update regarding Prospective Drug Utilization Review Criteria implemented July 2012. Donna Clay, BSPharm, reviewed Prior Authorization requests from July 2012 through June 2013 for Prospective Drug Utilization Review Criteria that were implemented July 2012 as part of SMART Act initiatives. The total number of Prior Authorization requests approved/denied and the number of patients impacted were reviewed for immunosuppressive agents used in transplant patients, erythropoiesis stimulating agents, hepatitis agents, the HIV agents enfuvirtide and maraviroc, and select oncology agents. A total of 6451 Prior Authorization requests for 4040 patients was received. The greatest number of Prior Authorization requests was received for hepatitis and erythropoiesis stimulating agents and the least for the HIV agents. Dr. Tulley asked about common denial reasons. Donna Clay, BSPharm, noted that many denial reasons are drug specific. Denials may be due to lack of required medical justification-laboratory monitoring information, patients not meeting criteria for use of an agent, or patient nonadherence to therapy with resultant lack of efficacy. If required medical data and sufficient justification is provided, requests are approved. The Prior Authorization process has helped identify cases of patient nonadherence to therapy early, which in turn has helped decrease development of resistance and therapeutic failure. This is a great benefit given the lack of remaining treatment options if patients fail therapy. Lisa Arndt, Bureau Chief BPS, also noted that appropriate use is cost effective for the health care system long term.

Simvastatin-calcium channel blocker interaction. Christina Petrykiw, PharmD, reviewed information regarding simvastatin and calcium channel blocker (CCB) interactions that was requested by DUR Board members at the April 17, 2013 meeting. Concern with statin interactions relates to potential adverse reactions such as increased creatinine kinase levels, myalgia, myopathy, myositis, rhabdomyolysis, and acute renal failure secondary to myoglobinuria with potential death. A claims processing drug utilization control edit is in place for the interaction of simvastatin and gemfibrozil, a contraindicated combination because monotherapy with each agent can cause myopathy/rhabdomyolysis. If the drugs are combined, gemfibrozil inhibits simvastatin metabolism, increasing systemic simvastatin levels and resultant adverse events. Atorvastatin, lovastatin, simvastatin, and the CCBs are cytochrome p-450 3A4 isoenzyme (cyp3A4) substrates, thus more subject to cyp3A4-mediated pharmacokinetic metabolic interactions. Additionally, diltiazem and verapamil are weak inhibitors of cyp3A4. The interaction with CCBs is in part dependent on stain potency or high dose and exacerbated by pharmacokinetics. Combination simvastatin and CCB therapy is not contraindicated because only simvastatin causes rhabdomyolysis. Simvastatin dose adjustments help decrease systemic levels. Extensive literature addresses the pharmacokinetic interaction of statins and CCBs, but clinical significance remains unclear due to low reports of adverse effects with combination therapy. The FDA Adverse Event Reporting System (FAERS) incidence of rhabdomyolysis in statin-treated patients is 0.7 per 100,000 patient years. Adverse reactions may occur at lower doses with combination therapy, are not decreased with long-term use, may be independent of kinetics in patients with a genetic predisposition, and are increased in older patients. In cases of hospitalization due to rhabdomyolitis with statins, patients were receiving statin monotherapy or combination therapy with a fibrate. Increased use of medications for muscular complaints after starting statin therapy hints at potential need for further evaluation. Guidelines for managing statin adverse events recommend drug discontinuation, rechallenge with the same or different statin, or complete statin discontinuation depending on creatitine kinase levels and muscular symptoms. John Tulley, MD and Lori Wilken, PharmD, noted that most practitioners will not rechallenge with the same statin and patients are reluctant to try any statin after adverse effects have occurred. Interaction management includes use of appropriate simvastatin doses and preferentially using statins not metabolized by cyp3A4. Patients who have experienced muscular adverse effects may need to have target lipid values reassessed.

Evaluation of HFS pharmacy claims from March 1, 2013 to May 31, 2013 identified 809 patients taking combination therapy with simvastatin and CCBs (3% of all CCB and almost 4% of all simvastatin prescriptions for

the same time period). Simvastatin doses ranged from 5 mg to 80 mg. Concomitant CCBs included amlodipine, diltiazem, felodipine, verapamil, and nifedipine. If combination therapy is necessary, recommended doses for simvastatin are 20 mg when administered with amlodipine (110 patients exceeded recommendation) or when administered with dual amlodipine-diltiazem therapy (5 patients exceeded dose). Simvastatin 10 mg is the maximum recommended dose if administered with diltiazem (28 patients exceeded dose) or verapamil (19 patients exceeded dose). The maximum recommended diltiazem dose with combination simvastatin therapy is 240 mg (15 patients exceeded dose). HFS does not recommend instituting a hard edit for combination simvastatin and CCB therapy at this time due to low number of patients impacted. Providers of patients who are receiving greater than recommended doses will be educated as time allows. Education will be incorporated into ongoing call-outs to providers of patients taking simvastatin 80 mg. DUR Board members agreed that educational intervention was most appropriate at this time. Dr. Tulley noted that clinically it may be appropriate to increase doses if needed for hyperlipidemia or hypertension control in patients not experiencing muscular adverse effects who are monitored. Dr. Caskey asked whether preferred statins for use in combination with CCBs are those that are less lipophilic. Pravastatin and rosuvastatin are the hydrophilic statins that are mostly excreted as unchanged drug. Preferred statin choice is more based on the isoenzyme involved in hepatic metabolism, although lipophilicity may also play a role. Everyone was surprised at the low number of patients impacted given high statin and CCB prescription rates. Computerized drug interaction warnings that prompt changes to prescription orders and education that occurred after ceruvistatin removal from the market due to fatal rhabdomyolitis may account for this.

Educational initiatives

Doxycycline shortage. Donna Clay, BSPharm, reviewed the educational update for providers regarding the doxycycline shortage. Manufacturing issues have led to fewer suppliers and increased demand and price for solid oral dosage forms of doxycycline hyclate and monohydrate. Prior authorization criteria were implemented in March 2013 to help manage the shortage. Criteria incorporated the Centers for Disease Control and Prevention (CDC) recommendations for limiting doxycycline use to indications for which it is the preferred treatment option and no equally effective alternatives exist: granuloma inguinale, lymphogranuloma venereum, prophylaxis and treatment of Lyme disease and malaria, and Rickettsial infections. Information with recommendations for other preferred therapy was also provided for select common indications where high doxycycline use exists. Dr. Tulley questioned the lack of information about treating community-acquired pneumonia (CAP) with doxycycline. The CDC did not list CAP as one of the conditions for which doxycycline is the preferred treatment option, most likely because other treatments are available to fill the void. Doxycycline is usually considered an alternative, not preferred agent in the treatment of CAP. Anitha Nagalli, PharmD, noted that limited doxycycline hyclate is available, but is expensive.

Website hits for educational items. The counter set on the DUR Web page was implemented April 25, 2013 to count the number of times the page is loaded in the browser as a direct link or from another page. It does not count the number of times each educational PDF document on the page is accessed. For the counter to effectively provide information about accessing materials, links should be sent for the page, not direct links to the PDF files. The page has been accessed a total of 648 times from April 25, 2013 through June 30, 2013 (April 46 times; May 327 times; June 275 times). The counter can not determine who is viewing the page. A link to the DUR Web page was added to the Resources section of the Search for Prior Approval Status by Drug Web page.

Professional local meetings for educating providers about HFS initiatives. Members were provided with resource documents for determining venues for HFS and DUR-related educational presentations. The first document lists national and Illinois-based healthcare provider associations with meetings scheduled in Illinois through 2014. The second document describes the organizations and their target audience.

Education to be conducted related to pain management. The link to the article, *Enhancing Safety for Patients and Family Medicine Practices. Due Diligence in Prescribing Narcotics/Opioids and other Controlled Substances*, is live in the education section of the DUR Web page.

Mary Lynn Moody, BSPharm, asked DUR Board members about desired educational initiatives regarding pain management. Dr. Goyal recommended using readily available federal and medical society educational and certification programs for narcotic prescribing. He suggested DUR Board members review programs to determine if they would meet our needs. Our role may be better served promoting the readily available programs, instead of creating programs. Donna Clay, BSPharm, noted that pain management program renewal requests reveal more

patient referrals to pain specialists and clinics. Provider-patient opioid treatment agreements (pain contracts) are on file for many patients taking narcotics chronically. Fewer renewals than anticipated are requested, so the Illinois Prescription Monitoring Program (ILPMP) is being checked to see if patients are paying cash for their narcotics, rather than receiving them through Medicaid via a renewal request. Overall, narcotic use has decreased in Illinois Medicaid patients. Dr. Goyal asked whether providers supply urine drug test reports or if HFS verifies that physicians are checking the ILPMP registry. Donna Clay, BSPharm, stated that the pain management program renewal letter of medical necessity for long-term opioid use requires the date the ILPMP registry was checked for the patient. Provision of drug urine test results is not currently required for the pain management program. The pain contract incorporates consent for random blood or urine drug screening. For Suboxone prior authorization, the ILPMP check date, data learned, and results from a urine drug screen within the past 14 days are required. Dr. Caskey questioned the benefit of requiring submission of urine test results for the pain management program. Dr. Goyal noted that it may be easy to say it is done, but education and compliance are expedited by asking for test results. Concerns relate to medication compliance versus drug diversion. This could help decrease inappropriate usage further. Dr. Tulley commented that benefit compared to increased workload burden on physician practices must be considered.

Dr. Goyal asked DUR Board members for input for a Task Force report due September 1, 2013 that is addressing improving detoxification processes in Illinois. The Division of Alcohol and Substance Abuse **(**DASA) is considering reopening methadone clinics in Illinois. John Tulley, MD and Rachel Caskey, MD, noted the issue is definitely controversial. Dr. Goyal highlighted the positive aspects that Illinois has experience with methadone clinics and that methadone may be a less expensive treatment option. DASA requires provider certification. A special license is required for methodone prescribers. The process is very controlled. Novice methadone prescribers are not eligible. Negative aspects include communities not wanting a clinic in their area because historically many clinics were closed due to diversion and abuse. Dr. Caskey noted that medical providers will want to know efficacy data regarding the clinics.

Comments from interested parties.
There were no comments or questions from interested parties present at the meeting. Dr. Caskey asked about the anticipated implementation date of the Four Prescription Policy in pediatric patients. Patricia Steward, BSPharm, stated that the start date has not been finalized.

Adjournment. Dr. Tulley moved to adjourn the DUR Board meeting and Dr. Nagelli seconded the motion. Members unanimously agreed and the DUR Board meeting was adjourned at 9:04 am.

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

Approved 10/23/2013 by the Illinois Drug Utilization Review Board.