ILLINOIS DEPARTMENT OF Healthcare and Family Services
201 South Grand Avenue East
Springfield, Illinois 62763-0002

Bruce Rauner, Governor
Felicia F. Norwood, Director
Telephone: (217) 782-1200
TTY: (800) 526-5812

Drug Utilization Review Board
Meeting Summary
Wednesday, September 23, 2015

The Drug Utilization Review (DUR) Board met on Wednesday, September 23, 2015, 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: 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); Arvind K. Goyal*, MD, Medical Director, Medical Programs, HFS; Kathy Kasiurak, PharmD, UIC; Christina Petrykiw, PharmD, CDE, UIC; Linda Schuh*, BSPharm, HFS Bureau of Professional and Ancillary Health Services (BPAS); Patricia Steward*, BSPharm, BPAS; Katherine Zych, PharmD, UIC.

Interested parties: Nick Boyer, Otsuka; Christine Bobowski, PharmD candidate, UIC College of Pharmacy; Lisa Dunn, Amgen; David Large, Supernus; Michael Larond, Abbvie; Ashley Polce, Abbvie; Mike Sima, Alkermes; David Skibicki, Pfizer; Dave Sproat, Bristol-Myers Squibb; Gary Thurnauer, Pfizer.

*Attendance via teleconference

Call to Order. Rachel Caskey, MD, called the meeting to order on September 23, 2015 at 8:31 am.

Agenda, conflict of interest review, and approval of May 20, 2015 meeting minutes. Illinois DUR Board members had no changes to the September 23, 2015 meeting agenda or the May 20, 2015 minutes. Lori Wilken, PharmD, made a motion, seconded by John E. Tulley, MD, and the DUR Board unanimously approved the May 20, 2015 minutes. Rachel Caskey, MD, 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.

Department of Healthcare and Family Services, Bureau of Professional and Ancillary Health Services report. Linda Schuh, BSPharm, informed members that there was no report at this time.

Prospective Drug Utilization Review

Narcotic Duplicate Therapy edit. Christina Petrykiw, PharmD, notified the DUR Board members that tramadol, a centrally-acting synthetic opioid analgesic, has been added to the existing narcotic duplicate therapy edit effective August 10, 2015. This is part of ongoing efforts to ensure appropriate narcotic therapy for pain management. Tramadol is also included in the monthly quantity edit of 186 total units of narcotics dispensed in 30 days.

Testosterone. Katherine Zych, PharmD, provided an overview of testosterone therapies, including testosterone in oral, topical, and injectable formulations, oral fluoromesterone, and methyltestosterone. These products are used to treat hypogonadism due to certain medical conditions, delayed male puberty, and metastatic breast cancer in females. Signs and symptoms are similar in primary and secondary hypogonadism. The Endocrine Society recommendations for androgen deficiency and hypogonadism in HIV-infected men as well as the National Comprehensive Cancer Network® (NCCN®) guidelines for Stage IV breast cancer (recurrent metastatic disease) were reviewed. Potential adverse reactions help guide Endocrine Society recommendations for situations where testosterone therapy should be avoided. Potential safety issues with testosterone therapy include a high potential for misuse, abuse, or diversion,

which is why testosterone therapies are classed as Drug Enforcement Agency (DEA) Controlled Substance Schedule III. The Food and Drug Administration (FDA) recently focused on increased cardiovascular risk with testosterone therapy and lack of benefit from testosterone therapy for hypogonadism due to aging. Recent studies demonstrate an increased risk of heart attacks, strokes, or death with testosterone therapy. Providers should be educating their patients regarding potential cardiovascular risk before starting or continuing testosterone therapy. Review of testosterone utilization demonstrates up to 640 participants treated with testosterone annually from 2010 to 2013 and then decreases in numbers of participants treated in 2014 and again in 2015. The decrease in usage may be due in part to shift of patients to managed care that started in 2013 and the FDA warnings about cardiovascular effects that were first highlighted in 2014. Dr. Goyal, MD, asked whether the utilization numbers for 2014 and 2015 included utilization at Managed Care Organizations. Christina Petrykiw, PharmD, noted that although we know when participants shift to managed care, we do not get detailed claims data. Thus the numbers reflect only usage in fee-for-service clients. The non-injectable testosterone products are mainly used. Usage shifts for testosterone patches, topical gels, pump products, and nasal solutions are evident as new product formulations become available. The FDA's cardiovascular warnings for testosterone prompted a review of existing prior authorization criteria. Testosterone is approvable for hypogonadism for certain medical conditions, but not in males with prostate or breast cancer, unexplained elevations in prostate-specific antigen levels, unevaluated prostate nodules or indurations, severe lower urinary tract symptoms, untreated sleep apnea, uncontrolled heart failure, or erythrocytosis with a hematocrit level > 50%. Approvable indications parallel existing Endocrine Society guidelines. Providers need to submit clinical documentation, two total testosterone levels and a free testosterone blood level drawn between 8 am and 10 am on separate days, and current hemoglobin and hematocrit levels. Similar documentation is required for renewal requests. Of the 1,263 prior authorization requests received during state fiscal year 2015, approximately 23% of the requests were approved. Primary reasons for denials included insufficient medical documentation, blood levels drawn at inappropriate times, approvals already on file, and changes in insurance coverage. The DUR Board members discussed lack of testosterone therapy efficacy for age-related hypogonadism. Board members asked whether an age breakdown for clients requesting the testosterone therapies was available. Lori Wilken, PharmD, and Anitha Nagelli, PharmD, noted the potential benefits for providers of posting the fax back form or testosterone criteria on the HFS Prior Authorization Web. John Tulley, MD made a motion to approve the testosterone criteria that was seconded by Lori Wilken, PharmD. The DUR Board unanimously approved the prior authorization criteria for testosterone.

Retrospective Drug Utilization Review

Synagis. Christina Petrykiw, PharmD, provided an overview of Synagis, the monoclonal antibody indicated for prevention of serious lower respiratory tract disease caused by Respiratory Syncytial Virus (RSV) in children at high risk of RSV disease. Prior authorization criteria were updated in 2014 based on new American Academy of Pediatrics Committees' guidelines for palivizumab prophylaxis in infants and young children at high risk of hospitalization for RSV infection. The average RSV season, for which Synagis may be administered, is between November and March. During the 2014-2015 RSV season, HFS received 1,065 prior authorization requests - approximately 50% fewer requests received compared to the 2013-14 RSV season. About 59% of the requests received for Synagis in the 2014-2015 season were approved. Approximately 4% of participants for whom Synagis was requested were hospitalized for RSV-related infection, acute bronchiolitis, or pneumonia. At least 57% of these participants had a Synagis approval on file. Of the participants for whom Synagis was approved, only 16% received all 5 doses of Synagis. Approximately 11% of participants for whom Synagis was requested were hospitalized for non-RSV respiratory conditions (acute bronchitis, acute bronchiolitis due to other infectious organisms, viral pneumonia, bronchopneumonia, organism unspecified, pneumonia, organism unspecified [participants did not have influenza or bacterial pneumonia]). At least 73% of these participants had Synagis approved. Some participants in all groups were hospitalized more than once. Similar to the 2013-14 season, more participants with Synagis approvals than denials were hospitalized. In the 2014-15 season almost twice the number of participants as in the 2013-14 season for whom Synagis was requested transferred to managed care during the RSV season. The DUR Board members noted that although changes in criteria and movement to managed care decreased the number of participants for whom Synagis was requested, percent of hospitalizations did not increase in participants denied Synagis. Christina Petrykiw, PharmD, noted that participants for whom Synagis was approved met criteria and thus may be children with significant medical co-morbidities. The increased number of hospitalizations with Synagis approved-participants is then not surprising. The DUR Board members agreed that since there were no guideline updates in 2015 and no significant patient-related issues due to the changed criteria in the last RSV season, that the criteria should remain the same for the 2015-2016 RSV season. The Synagis Prior Authorization criteria and request form are posted on the HFS Prior Authorization Website.

Non-steroidal anti-inflammatory drugs (NSAIDs). Christina Petrykiw, PharmD, addressed the recent safety update from the Food and Drug Administration (FDA) regarding NSAIDs. The NSAID formulations that are preferred were noted. In 2005, the FDA had required a boxed warning for NSAIDs regarding increased risk of heart attack and stroke that can lead to death in patients taking NSAIDs. In February 2014, the FDA Arthritis and the Drug Safety and Risk Management Advisory Committees reviewed the NSAID studies that implicated the increased risk. In July 2015, the boxed warning was strengthened. Cardiovascular events may occur within the first few weeks of NSAID therapy. Risk increases with longer duration of therapy. The risk is greater and more consistent at higher NSAID doses. Although the increased risk is evident with and without past medical history of a myocardial infarction or risk factors for heart disease, baseline risk is elevated in patients with history or risk factors. Some studies indicated differences in risk among the NSAIDS, but there is insufficient data to support this claim. The range of cardiovascular events ranges from10% to 50% depending on the NSAID or doses studied. Following a first heart attack, patients treated with NSAIDs other than aspirin, are more likely to die in the first year after the myocardial infarction, compared with patients who did not take a non-aspirin NSAID. Non-aspirin NSAID use also increases the risk of heart failure. The non-aspirin NSAIDs may interfere with low-dose aspirin's antiplatelet action due to NSAID-induced blockade of aspirin's irreversible COX-1 inhibition. The FDA is now requiring updates to prescription and over-the-counter (OTC) NSAID labels. Recommendations for health care providers include using the lowest effective NSAID dose for the shortest duration possible, increased alertness for cardiovascular symptoms in all patients taking NSAIDs at any time, and provision of the most recent Medication Guides when NSAIDs are prescribed. Patients are advised to seek immediate care for symptoms of heart attack or stroke. Currently, HFS has monthly quantity limits for single and combination therapy NSAIDs, duplicate therapy edits, and requires prior authorization for 6 of 18 NSAID entities currently available by prescription. The OTC NSAIDs are not covered by HFS. The DUR Board discussed whether a more in-depth retrospective review of NSAID use in HFS participants was warranted. Evaluation of doses used would be complicated by the lack of OTC coverage - this may drive prescribers to use the covered higher dosage strengths available with a prescription. Knowledge of OTC use in HFS participants is lacking. The DUR Board members were interested in learning how long HFS participants were filling a NSAID. They also wanted to know the incidence of myocardial infarction, stroke, or heart failure in HFS participants after they started NSAIDs and whether a temporal relationship existed between NSAID fill and cardiovascular event. Based on results of the retrospective data review, the DUR Board will determine whether an edit and/or education for providers should be implemented.

Educational initiatives.

Christina Petrykiw, PharmD, presented the educational items created by the Medication Review and Academic Detailing unit for the recent state pharmacy association member meetings.

Type 2 Diabetes. This educational item reviews diabetes goals and medication-treatment guidelines, preferred medication status, and HFS recommendations, which reinforce first-line status of metformin and medication adherence to therapeutic doses before therapy escalation. The DUR Board members appreciated the adherence focus. Anitha Nagelli, PharmD, made a motion to approve posting the educational item on the DUR Website, which was seconded by Lori Wilken, PharmD, and unanimously approved by the DUR Board.

High cholesterol: Using non-statins. This educational item reviews published clinical evidence and guidelines for impact on morbidity and mortality of using the non-statins to treat high cholesterol. Additionally preferred status of medications to lower cholesterol and HFS recommendations for use of non-statins are noted. The DUR Board members recommended including a link to risk calculators that determine 10-year risk for heart attack and stroke and inclusion of data related to use of Omega-3 fatty acids. Anitha Nagelli, PharmD, made a motion, seconded by Lori Wilken, PharmD, to post the educational item on the DUR website once the changes are made. The motion was unanimously approved by the DUR Board members.

Public comments. There were no public comments.

Adjournment. Rachel Caskey, MD, adjourned the DUR Board meeting at 9:30 am.

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

Approved February 17, 2016 by the Illinois Drug Utilization Review Board.