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# Drug Utilization Review Board
# Meeting Summary

## Wednesday, October 23, 2013

The Drug Utilization Review (DUR) Board met on Wednesday, October 23, 2013, at 8:00 a.m. in the B-16 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; John E. Tulley, MD; Lori Wilken, PharmD, AE-C. Absence of Anitha Nagelli, PharmD, M.Ed, Vice-chairperson, was excused.

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; Mark Huston*, HFS BPS; Mary Lynn Moody, BSPharm, UIC; Christina Petrykiw, PharmD, CDE, UIC; Linda Schuh*, BSPharm, HFS BPS; Patricia Steward*, BSPharm, HFS BPS; and Bertha Wallace*, HFS BPS.

Interested parties: Brian Groch, Hyperion; Jennifer Davis, ThromboGenics; Palak Desai, WellCare; John Dullard, Amgen; Tom Erikson, BMS; Chris Gillette, Pfizer; Jeff Himmelberg, GlaxoSmithKline; Lee Hennigan, GlaxoSmithKline; Michael Lafond, AbbVie; Deborah Mance, Hyperion; Terry McCurren, Otsuka; Sam Smothers, MedImmune; Gary Thurnauer, Pfizer; Bob White, Forest Pharmaceuticals; Lisa Willshaw, MedImmune.

*Attendance via teleconference

**Call to Order.**
Rachel Caskey, MD, called the meeting to order on October 23, 2013 at 8:07 am.

**Agenda and Minutes review**.
No changes were suggested to the agenda or 8/21/2013 meeting summary. John Tulley, MD made a motion to approve the summary of the August 21, 2013 meeting. Rachel Caskey, MD, 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.**

Mark Huston, HFS BPS, provided an update on new initiatives at the HFS Bureau of Pharmacy Services. The Four Prescription Policy expansion to children is anticipated at the end of November 2013. Medicaid covers prescriptions for approximately 16,000 children. Providers will receive a notice with the start date. Initially children ages 12 to 18 years of age will be incorporated. Calls to providers of children who fill more than four prescriptions monthly are addressing medication-related issues, such as duplicate strengths and dosage forms for the same medication. Often several medication strengths are approved initially to facilitate titration to appropriate doses. At this time consolidation of doses is being attempted. Lurie Children's Hospital in Chicago and St. Louis Children's Hospital have started submitting Four Prescription Policy requests via the Medical Electronic Data Interchange (MEDI). Mary Lynn Moody, BS Pharm, reminded everyone that children are not limited to four prescriptions monthly, rather after four prescriptions have been filled, a medication review is prompted so that the provider can assess what medications are currently needed for the patient.

John Tulley, MD asked about measuring cost-shift impact related to the Four Prescription Policy from use of medications/pharmacy services to increased use of emergency, medical, or hospital services. Mark Huston, HFS BPS, noted the up-to 6-month delay of obtaining medical claims data compared with point of service pharmacy claims data. The Appropriations Meeting in Springfield noted no significant shift to increased use of Emergency

Room or hospital services after implementation of the Four Prescription Policy. Actual medication-related savings are being evaluated. Discontinuation of auto-refill by pharmacies and decreasing duplicate prescriptions contribute greatly to cost savings. Rachel Caskey, MD is noticing fewer narcotic requests in her practice. The DUR Board members requested cost-shift information once it becomes available.

Arvind Goyal, Medical Director, informed DUR Board members that HFS Bureau of Pharmacy Services has not received complaints regarding negative effects of the Four Prescription Policy or increased medical, Emergency Room, or hospital visits. The majority of complaints have related to request submission. Mark Huston, HFS BPS, noted that access problems for submitting Four Prescription Policy requests have been resolved. Requests called into the Hotline or sent in via fax are entered within 1-1.5 hours and then adjudicated within 2 hours of data entry. If a request is submitted via MEDI, there is no data entry delay and the request goes directly to adjudication, saving up to 2 hours. Mary Lynn Moody, BSPharm mentioned that providers can now also view denial reasons and adjudication notes via MEDI. Four Prescription Policy submissions via fax or hotline account for 70% of requests, while 30% are submitted electronically via MEDI. Facilities and medical practices not submitting requests electronically have been identified and live MEDI training/educational will be conducted in Peoria and East St. Louis soon. Mark Huston, HFS BPS, stated that the initial MEDI registration is time consuming, but once completed, MEDI use is appreciated, particularly the ability to see request status.

**Drug Utilization Review Board Administrative Issues**

**Training**. DUR Board members must complete the annual *Ethics Training for appointees to State of Illinois Boards*. Training materials were sent electronically to DUR Board members. Completion of other, ie. university-required Ethics Training does not fulfill this training requirement. Signed and dated Acknowledgement of Participation in Ethics Training forms should be submitted to Christina Petrykiw, PharmD, as soon as completed.

**DUR Board meeting schedule for 2014.** The proposed meeting schedule for 2014 was presented. Start time was changed to 8:30 AM to facilitate meeting attendance and other commitments of DUR Board members. The August meeting was moved to July to allow two months between meetings. Dr. Tulley made a motion to approve and Rachel Caskey, MD seconded the motion to approve the DUR Board meeting schedule for 2014. The schedule was unanimously approved. The schedule will be posted January 2014 on the HFS DUR Board Webpage.

**Drug Utilization Review**

**Synagis.** Donna Clay, BSPharm, reviewed the prior authorization process for palivizumab (Synagis), which is indicated for prevention of serious lower respiratory tract disease caused by Respiratory Syncytial Virus (RSV) in children at high risk of RSV disease. Synagis was approved in 1998. Illinois Medicaid has required prior authorization for Synagis since 2002. The University of Illinois Prior Authorization Group has conducted prior authorization for Synagis since the 2007 season. Synagis Prior Authorization criteria and request form are posted on the HFS Website. Criteria reflect American Academy of Pediatrics (AAP) recommendations for use of palivizumab for prevention of RSV infections. Two changes to the criteria have been implemented for the November 2013-April 2014 RSV season to ensure consistency with the modified AAP recommendations (Pediatrics 2009;124 :1694-1701). Children less than 35 weeks gestation that were previously allowed five Synagis doses will now receive a maximum of three doses depending on their gestational age and the multiple birth risk factor has been deleted. Analysis of Synagis utilization demonstrates the number of patients for whom Synagis is approved has decreased since application of AAP recommendations to 1600-1700 patients annually. Synagis prior authorization requests for the current RSV season have been accepted since October 15, 2013. To date 550 requests have been received.

**Vitamin D (ergocalciferol).** Christina Petrykiw, PharmD, reviewed clinical use guidelines and Medicaid coverage for ergocaciferol, which is available as vitamin D2 50,000 unit (1.25 mg) capsules via prescription and smaller over-the-counter (OTC) strengths. Vitamin D3 is available as OTC cholecalciferol alone or in combination with calcium, while the active form of vitamin D3, calcitriol, is available via prescription only. Provitamin D3 in the skin converts to cholecalciferol following exposure to sunlight. Ergocaliferol and cholecalciferol undergo hepatic metabolism and renal conversion to calcitriol. The Food and Drug Administration (FDA) approved 50,000 unit ergocalciferol (Drisdol) for the treatment of hypoparathryroidism, refractory/vitamin D resistant Rickett's, and familial hypophosphatemia. Reported non-FDA labeled uses include prevention of osteoporosis-related fractures,

muscle weakness, falls, psychiatric illnesses, cardiovascular diseases, malignancies, diabetes, inflammatory bowel disease, respiratory conditions, multiple sclerosis, and rheumatoid arthritis. Patients at risk for low vitamin D levels include renally impaired, obese, or pregnant patients, those taking glucocorticoids, patients with higher melanin levels, and persons with no sunlight exposure or who have low lifetime intake of vitamin-D containing foods. The AAP recommends 400 IU daily vitamin D intake for children and hydroxyvitamin D [25(OH)D] blood levels of 20 ng/mL. Institute of Medicine (IOM) Recommended Dietary Allowances for vitamin D are 400 IU daily for infants, 600 IU daily for persons 1 to 70 years of age and pregnant or lactating women 14-50 years of age, and 800 IU daily for patients 70 years of age and older. The Endocrine Society recommends hydroxyvitamin D levels over 20 mg/mL for bone health. Levels less than 20 mg/mL indicate vitamin D deficiency and levels 21-20 ng/mL indicate insufficiency. Vitamin D 50,000 IU is recommended once weekly for 8 weeks to achieve levels greater than 30 ng/mL. Afterwards, maintenance therapy with 1,500-2,000 IU daily is recommended. Dosing for vitamin D insufficiency parallels IOM recommendations. The K/DOQI guidelines for patients with chronic kidney disease also delineate hydroxyvitamin D levels for vitamin D insufficiency and deficiency. Monthly therapy for 6 months is recommended for insufficiency. For deficiency, weekly therapy for 4-12 weeks depending on severity, and then monthly for 6 months is recommended. The United States Preventive Services Task Force does not recommend daily supplementation with vitamin D and calcium for primary prevention of fractures in noninstitutionalized postmenopausal women. They do recommend vitamin D 800 IU supplementation for prevention of falls in community-dwelling adults aged 65 years and older who have an increased risk for falls due to history of recent falls or vitamin D deficiency. The American Society for Clinical Pathology recommends hydroxyvitamin D testing in higher risk patients when results will be used to institute more aggressive therapy. Medicare Part D does not cover ergocalciferol. State Medicaid programs vary in their coverage for various dosage forms, quantities, and patient eligibility levels. Utah covers vitamin D and calcium therapy in patients taking bisphosphonates. Texas and Alaska require prior authorization for ergocalciferol 50,000 IU and approve for 6 or 12 months, respectively. Alaska approves for FDA-labeled indications after 6 months of OTC doses of vitamin D fails to correct the deficiency based on laboratory findings, while Texas expands the list of approved indications.

Illinois Medicaid approved Vitamin D preparations for 59,712 patients in 2012, paying $2.4 million in claims. At least 135,303 prescriptions have been filled for Illinois Medicaid patients this year through August 2013. Over 5,331 Four Prescription Policy requests have been received for ergocalciferol 50,000 IU from October 1, 2012 through October 17, 2013. Sixty-seven percent of requests have been approved, with 839 denials for insufficient medical justification. At least 730 faxes have been sent providers to notify them of the 3-month approval and current guidelines for therapy. Ergocalciferol 50,000 IU is currently approved for 1 year for patients with chronic kidney disease or parathyroid hormone deficiency and for 3 months for low vitamin D levels. After 3 months, levels must be submitted to document continued need or patients may self-pay for OTC vitamin D. The DUR Board agreed that vitamin D requests should continue to be reviewed and approved for 3 months with vitamin D levels requested as appropriate. Although faxing is not ideal, it is currently one of the available methods to reach out to providers until a more robust computer system with alerting capability is implemented. The DUR Board unanimously approved ergocalciferol 50,000 IU for 1 year for patients with chronic kidney disease and hypoparathyroidism. Appropriate doses of vitamin D may be approved for 1 year for patients taking bisphosphonates and community-dwelling adults over 65 years of age who are at increased risk for falls based on a history of recent falls or vitamin D deficiency. Arvind Goyal, MD supported not requiring failure with OTC vitamin D therapy prior to erogocalciferol 50,000 IU as done in Alaska. Geriatric Board data confirms multivitamins should not automatically be given to all elderly patients, but that many frail elderly patients may require vitamin D therapy. The DUR Board members recommended using the DUR Webpage to post educational information regarding appropriate use of vitamin D as well as information about fall or frailty risk assessment tools.

**Inappropriate prescribing**. Mary Lynn Moody, BSPharm reviewed 17 cases of inappropriate prescribing of psychiatric medications identified through Four Prescription Policy prior authorization processes. Initital interventions were reviewed to determine acceptance and implementation of recommendations made to providers. Diagnoses for which inappropriate prescribing has been identified include anxiety, bipolar disorder, depression, schizophrenia and affective disorders that occur alone or as co-morbidities. Inappropriate prescribing occurs across all patient types, is not gender- or age-specific, and is not isolated to one class of medications or one type of prescriber (specialist psychiatrist or general practitioner). Cases of duplicate therapy involving two agents in the same pharmacologic class or agents that produce the same outcome via different mechanisms, and two

strengths/dosage formulations of the same agent have been identified. Duplicate therapy results from poor communication between providers and/or patients and providers. It is also a result of adding a new agent based on the assessment of lack of efficacy and assumption of therapy adherence, when in reality the original prescription was never filled. Patients may not understand that a new therapy is a substitute for a previous therapy and continue to take both therapies in the same pharmacologic class. Pharmacy auto-fill processes contribute to duplicate therapy, but have decreased as a result of the Illinois Medicaid Provider Notice issued 4/24/13 that informed providers that auto-filled products would not be reimbursed. Cases of inappropriate therapy may be associated with duplicate therapy and polypharmacy. Over- and under-utilization of therapy and prescribing the wrong therapy for the indication are also considered inappropriate therapy. Factors that contribute to inappropriate therapy include dispensing samples, self-pay by the patient, or therapy non-adherence. Overutilization of benzodiazepines is associated with overuse of one medication (600 tablets in 2 months) or use of multiple benzodiazepines for anxiety. Benzodiazepines' addictive potential increases risk of abuse or diversion. Often benzodiazepine therapy is relied on for long-term management of anxiety, with first line agents such as serotonin reuptake inhibitors (SSRIs) not being prescribed or taken. Illinois Prescription Monitoring Program (ILPMP) data reveals cases of self-pay that have contributed to overuse of benzodiazepines. Review of cases revealed physicians are often unaware of patient non-adherence to therapy or self-payment. Case review demonstrated potential complexity of managing patients with comorbid psychiatric conditions and benefits of periodic patient re-assessment to identify unresolved or new issues.

The DUR Board discussed how to best achieve the goal of improving prescribing for psychiatric medications in adult and pediatric patients. Arvind Goyal, MD asked how the cases of inappropriate prescribing were identified. The Four Prescription Policy review process generated these cases. Arvind Goyal, MD asked whether there could be a cultural medical practice change to check the ILPMP for patients taking multiple antipsychotic medications. There is interest in assessing how many Illinois Medicaid providers are registered and accessing ILPMP, since many of the patients taking multiple antipsychotic medications are self-paying for benzodiazepines and other therapies. A recent review of the vaccine registry noted that only 10% of prescribers are checking the registry. Donna Clay, BSPharm stated that checking ILPMP is required along with documentation of date and findings for Suboxone prior authorization requests. Prior authorization staff check ILPMP for benzodiazepine and narcotic requests and providers are informed of findings and encouraged to also check ILPMP. Mary Lynn Moody, BSPharm will check with ILPMP to determine percent of Illinois Medicaid providers that are registered and access the database. Lori Wilkin, PharmD, noted that the missing element is the patient who cannot state why they are not adherent with a medication as identified via claims data. Medication Therapy Management pharmacy sessions or medical clinic visits with patients provide this information. Christina Petrykiw, PharmD, recommended all providers who identify non-adherence or duplicate therapy communicate with other providers and discuss the issues with the patient. Although auto-fill contributes to inappropriate prescribing, DUR Board members noted seeing a decrease in auto-fill generated requests for Illinois Medicaid patients, but not for those covered by other commercial insurance providers. Rachel Caskey, MD, informed members about potential inaccuracy with data in the ILPMP database based on two cases in her clinic. Although ILPMP fixes issues quickly, inaccurate data may negatively impact patient interactions. Mary Lynn Moody, BSPharm, explained that HFS is working with Threshold, realizing that each patient is unique in their needs for psychiatric medications. Rachel Caskey, MD, and Mary Lynn Moody, BSPharm addressed the existence of psychiatric deserts in Illinois where psychiatrists are not available and psychiatric issues are managed only by family practice physicians. Consultation with pediatric psychiatrists is available to providers via the DocAssist program, an option shared with providers by Prior Authorization staff. Arvind Goyal, MD informed everyone that Illinois Medicaid covers telepsychiatry services.

**Educational initiatives**

DUR Board members appreciated the case reviews for inappropriate prescribing of psychiatric medications as well as the ergocalciferol presentation and noted that the presentations could be used for continuing education.

**Professional local meetings for educating providers about HFS initiatives**. Currently the primary goal is to train providers regarding MEDI to facilitate electronic submission. Pharmacist MEDI training occurred in September 2013 at the Illinois Pharmacists Association and Illinois Council of Health-System Pharmacists Annual Meetings, and with Walgreens and CVS. Medical and pharmacy training was completed at Rush Medical Center in Chicago. Upcoming training is planned for Crusader Clinic in Rockford, in Peoria, and St. Louis. The MEDI training has been useful for explaining the Four Prescription Policy and resulted in positive provider interactions. Focus is now

more on training physician providers as part of exhibit booths/tables at meetings or medical grand rounds. Memorial St. John's in Springfield will be one of the initial training sites with this model.

**Pain management education.** Previously, DUR Board members recommended promotion of currently existing pain management education programs, rather than program creation by HFS. Christina Petrykiw, PharmD, reviewed select pain education programs, including FDA required Risk Evaluation and Mitigation Strategies (REMS). A short REMS online program is available for transmucosal immediate-release fentanyl (TIRF) oral and sublingual dosage forms and there is a program for buprenorphine-containing Transmucosal products for Opioid Dependence (BTOD). Suboxone prescribers are already required to undergo certification to treat opioid dependence under the Drug Addiction Treatment Act 2000. The newest FDA REMS requirement addresses extended-release and long-acting opioid analgesics. Components of this REMS are provider self-training via completion of a REMS-compliant education program, patient counseling, emphasis on patient/caregiver understanding of required Medication Guides provided with dispensed prescriptions, as well as use of Patient Counseling Documents, Patient-Prescriber Agreements, and risk assessment instruments.The ER/LA Opioid Analgerics REMS Web page provides downloadable copies of materials and lists of accredited CME/CE REMS compliant activities supported by the REMS Program Committee (RPC) based on the FDA Blueprint for core educational messages for prescribers and proper prescribing practices. The database of accredited continuing education activities lists 70 approved education programs. It can be searched by type of activity (live vs online), state where activity is located, venue, and type of continuing education (CE) credit ie, CME, ACPE, AAFP, AANP, ADA. Five programs are available in the next few months in Illinois. DUR Board members were informed about pain-related continuing education programs available from the American Medical Association as well as Illinois and Utah State Medical Associations. Certification programs discussed included physician board certification via the American Board of Pain Medicine, the Illinois Academy of Family Physicians Safe Prescriber Program, American Academy of Pain Management Certification, and Registered Nurse Pain Management Certification. The Washington State Department of Health legislatively manages chronic noncancer pain. Washington Medical, Nursing, Dental, Osteopathic, and Podiatric Boards adopted rules regarding management of chronic noncancer pain. Consultation with a pain specialist is required if an adult requires a narcotic dose equal to or greater than a 120 mg Morphine Equivalent Dose. Depending on the discipline 12 to18 hours of CE over 2 to 3 years are required as well as one-time completion of at least 4 hours of CE related to long-acting opioids or methadone. Washington provides an opioid dosing guideline for chronic non-cancer pain. The DUR Board members recommended posting information regarding REMS education, pain-related CE, and pain certification in the education section of the DUR Website. Links or a provider notice regarding pain management should be posted on the Provider Websites also. The provider notice should include statistics gathered in the HFS Pharmacy Services Pain Management Program.

**Public comments**

Lisa Willshaw from MedImmune thanked HFS for covering Synagis for the prevention of RSV in high-risk children. She voiced concern regarding restrictions within the HFS Prior Authorization criteria related to use of less than 5 doses of Synagis in a season and specification of gestational age for patients with congenital or neuromuscular diseases who are candidates for palivizumab prophylaxis. Drug approval by the FDA was based on data from pivotal trials that used 5 doses for prevention within a season. The National Medical Association and National Perinatal Association issued statements regarding RSV and Synagis use. Clinical trials published since AAP recommendations for pavilizumab use were modified include a Danish study focused on recurrent wheezing in late preterm infants, a study addressing hospitalization rates in neonates born between 32-35 weeks gestation, and a Japanese study evaluating 3-year data in pateints with recurrent wheezing. MedImmunue requests reinstatement of 5 doses of palivizumab therapy in infants gestational age 32-35 weeks. Rachel Caskey, MD requested clarification of the extensive cost increase of Synagis for the current season. MedImmune representatives noted that their cost increase is once a year, rather than monthly during the RSV season, and market comparable.

**Adjournment.** Rachel Caskey, MD moved to adjourn the DUR Board meeting and John Tulley, MD, seconded the motion. Members unanimously agreed and the DUR Board meeting was adjourned at 9:36 am.

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

**Approved 1/15/2014 by the Illinois Drug Utilization Review Board.**