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Drug Utilization Review Board

Meeting Summary

Wednesday, October 22, 2014

The Drug Utilization Review (DUR) Board met on Wednesday, October 22, 2014, 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); Sheri Dolan*, BSPHarm, HFS Bureau of Professional and Ancillary Health Services (BPAS); Arvind K. Goyal*, MD, Medical Director, Medical Programs, HFS; Mary Lynn Moody, BSPHarm, UIC; Christina Petrykiw, PharmD, CDE, UIC; Linda Schuh*, BSPHarm, HFS BPAS; Patricia Steward*, BSPHarm, HFS BPAS.

Interested parties: Allyn Bandell, MedImmune; John Bullard, Amgen; Mark Davis, Vertex; Chris Gillette, Pfizer; Kevin Hamer, Impax; Lee Hennigan, GSK; Judy King, MD; Jeff Knappen, Allergan; Mike Krug, Sunovion; Michael Lafond, Abbvie; Terry McCurren, Otsuka; Jim McNamara, ViiV Healthcare; Scott Mills, Allergan; Ketul Patel, Vertex; Gary Thurnauer, Pfizer; Antoinette Sampson, AstraZeneca; Marla Wiedenmann, NovoNordisk Biopharm.

*Attendance via teleconference

Call to Order. Rachel Caskey, MD, called the meeting to order on October 22, 2014 at 8:30 am.

Agenda, conflict of interest review, and approval of July 23, 2014 meeting minutes. Illinois DUR Board members had no changes to the October 22, 2014 meeting agenda or to the July 23, 2014 minutes. Rachel Caskey, MD, called for a vote. John Tulley, MD, made a motion, seconded by Lori Wilken, PharmD, and the DUR Board unanimously approved the July 23, 2014 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. Patricia Steward, BSPHarm, notified the DUR Board that Lisa Arndt, Bureau Chief of Professional and Ancillary Health Services, which includes Pharmacy, has left HFS. The acting Bureau Chief is Gina Swehla, who has extensive public health and administrative experience, most recently with the HFS Dental Program. Mary Lynn Moody, BSPHarm, reminded pharmaceutical industry guests to not schedule meetings with Gina Swehla at this time, but to continue to meet with Sheri Dolan, BSPHarm, who can assist with most issues and escalate issues to the Bureau Chief as needed. No individual requests should be sent directly to the Bureau Chief at this time. Clinical issues can be addressed with Mary Lynn Moody, BSPHarm. Patricia Steward, BSPHarm, informed the DUR Board that recent legislation exempts medically fragile children from the Four Prescription Policy.

DUR Board meeting schedule for 2015. Christina Petrykiw, PharmD, presented the proposed meeting schedule for DUR Board meetings in 2015. Proposed dates will better facilitate discussion and approval of prospective DUR criteria. Rachel Caskey, MD, called for a vote and DUR Board members unanimously approved the 2015 schedule. Also, the DUR Board members will soon be receiving annual ethics training materials for 2014.

DUR Annual Report. The Drug Utilization Review Annual Report addresses the operation of Medicaid's DUR program for the previous DUR fiscal year. The report submitted September 2014 reflected the DUR fiscal year from

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10.22.14. Illinois Drug Utilization Review Board Meeting Summary

October 2012 through September 2013. The federally required report will be available for review on the [Medicaid Drug Programs Data & Resources Web page](#). When the live links are available, they will be sent to the DUR Board.

Prospective Drug Utilization Review

Final Drugs and Therapeutics Committee decisions for Preferred Drug List. Christina Petrykiw, PharmD, reviewed the medications for the Preferred Drug List (PDL) for which the Drugs & Therapeutics Committee rendered final decisions January through October 2014. The PDL decisions that require prior authorization for medications impact prospective DUR processes. Some preferred medications require prior authorization, primarily to ensure appropriate and safe medication use. Prior authorization requirements were removed for the injectable antifungals Ambisome and Mycamine to facilitate therapy for immunocompromised pediatric patients. Rachel Caskey, MD, asked whether all medications for which prior authorization is required have criteria. Mary Lynn Moody, BSP Pharm, noted that all will have criteria, but the criteria may not be very extensive. Anitha Nagalli, PharmD, asked whether all prior authorization criteria are posted online. Mary Lynn Moody, BSP Pharm stated that select criteria are currently posted, particularly if the medications have special forms that must be filled out.

Respiratory Syncytial Virus (RSV) prophylaxis. Christina Petrykiw, PharmD noted that the seasonal nature of RSV infection from November to March required updates of palivizumab (Synagis) criteria annually, particularly if new guidelines have been issued. New prior authorization criteria and forms as well as rounding criteria for palivizumab are posted on the HFS Prior Authorization Website. Donna Clay, BSP Pharm, reviewed the new criteria based on the American Academy of Pediatrics Infectious Diseases and Bronchiolitis Committees' guidelines that were published July 28, 2014. Palivizumab qualification for certain gestational ages was changed. Authorization forms have been accepted since October 15th via fax and since October 17th via MEDI for treatment start dates of November 1, 2014. Several hundred requests, including multiple duplicate requests have been received to date. Hospitalization statistics for clients for whom palivizumab was requested in the 2012 and 2013 RSV seasons were reviewed. Overall there were 96 fewer prior authorization requests for palivizumab in 2013 compared with the 2012 season. The majority of requests for palivizumab were approved in both seasons. Total hospitalizations for RSV and non-RSV respiratory conditions that potentially may be RSV were about 15% in both seasons. In each season, approximately 4% to 5% of patients were admitted due to RSV or RSV acute bronchiolitis/pneumonia, and approximately 12% of clients were admitted for non-RSV respiratory conditions (acute bronchitis or bronchiolitis due to infectious organisms, viral pneumonia, and bronchopneumonia or pneumonia due to unspecified organism). **RSV hospitalizations and palivizumab approval status.** Hospitalizations for RSV in clients for whom palivizumab was approved occurred in 4.46% of clients in the 2012 season and for 3.52% of clients in the 2013 season. Although palivizumab was approved, not all clients filled the medication. Five of 145 clients approved who did not fill palivizumab were hospitalized in 2012 and one of 147 clients in 2013. Hospitalizations in clients for whom palivizumab was denied occurred in 6.27% of clients in the 2012 season and 4.37% of clients in the 2013 season. **Non-RSV hospitalizations and palivizumab approval status.** Among approved clients, 11.87% in the 2012 season and 12.45% in the 2013 season were hospitalized for non-RSV respiratory disorders. Less than one percent of approved clients who did not fill prescriptions were hospitalized in both seasons. Eleven percent of clients denied palivizumab in the 2012 season and 9% of clients in the 2013 season experienced non-RSV hospitalizations. Criteria changes in 2013 did not result in an increase in hospitalizations. Lori Wilken, PharmD, relayed pediatric pharmacists' concerns about the current oxygen percent requirement, which is often not available after discharge. Donna Clay, BSP Pharm, noted that oxygen percent is required in the first year of life in diagnosing chronic lung disease of prematurity. Prior authorization staff works with providers case by case to ascertain oxygen use in older clients. Rachel Caskey, MD, mentioned that knowledge of continuous oxygen use for 6 months may be more reasonable than exact daily percent of oxygen use.

Cystic Fibrosis. Christina Petrykiw, PharmD, reviewed pathophysiology and management of cystic fibrosis (CF), which is caused by mutation of the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Lung disease primarily contributes to mortality in CF. Standard treatment incorporates bronchodilators, inhaled antibiotics (tobramycin), recombinant human DNase (dornase alfa), and inhaled hypertonic saline. Initial and renewal prior authorization criteria for tobramycin inhalation powder (Tobi Podhaler), which is an alternative dosage form to nebulized tobramycin, and for ivacaftor (Kalydeco) – a CFTR potentiator, were reviewed. Prior authorization was recommended by the Drug & Therapeutics Committee. Tobramycin Podhaler offers convenience, particularly with travel, compared with nebulization. Ivacaftor is indicated for patients with select CFTR genetic mutations and is not effective for the homozygous F508del mutation of the CFTR gene. Rachel Caskey, MD, inquired whether all standard treatments must be tried to be eligible for ivacaftor, since use of hypertonic saline and its efficacy are currently

10.22.14. Illinois Drug Utilization Review Board Meeting Summary

controversial, although still listed in current treatment guidelines. Donna Clay, BSPHarm, explained that each case is addressed individually. The expectation is an adequate trial of all standard therapies in patients for whom it is appropriate. Standard treatments are used concomitantly during ivacaftor therapy also. Ten of twelve requests received were approved. The 2 denials related to lack of current Medicaid eligibility, not clinical reasons. Arvin Goyal, MD, informed DUR Board members that legislative inquiries were received regarding ivacaftor in the last two days. Donna Clay, BSPHarm, noted that although few patients have the genetic mutations for which ivacaftor is presently approved, ongoing trials are assessing efficacy in other mutation types. Ivacaftor was FDA-approved for one genetic mutation in January 2012 and indications expanded to additional mutations in February 2014. Some HFS clients have taken ivacaftor for over a year. Rachel Caskey, MD, called for a vote and the DUR Board unanimously approved criteria.

Retrospective Drug Utilization Review

Hemophilia Care Management Program. Christina Petrykiw, PharmD, provided an overview of hemophilia and the HFS Hemophilia Care Management Program administered by Sheri Dolan, BSPHarm. Hemophilia, an X-linked congenital bleeding disorder, is caused by deficiency of coagulation factor VIII (hemophilia A) or factor IX (hemophilia B). Clotting factor levels and episodes of spontaneous bleeding are used to characterize severity of disease. Severe forms are often diagnosed at birth to the first month of age, while moderate and mild forms can be diagnosed at 8 or 36 months, respectively. Bleeding into joints or brain can cause lifelong chronic complications. Goals of treatment target preservation of musculoskeletal function as well as prevention of bleeding and joint damage by maintaining clotting factor levels at or greater than 1 IU/dL. Prophylaxis prevents bleeding episodes and can slow progression, but not reverse joint disease. Adjunctive therapies include desmopressin, antifibrinolytic medications, COX-2 inhibitors, narcotic pain medications for joint or muscle bleeding, non-pharmacologic therapy, and potentially surgery for complications. Blood factor replacement protocols include episodic treatment and continuous prophylaxis. Clients with Hemophilia A may receive factor 3 times a week, while those with hemophilia B may be infused twice a week. Dosing depends on factor administered, age, bleeding phenotype, venous access, patient activity, and product availability. Patients are taught at 6-10 years of age to infuse factor in the home setting to facilitate independence. The *Illinois Hemophilia Care Act* established 6 treatment centers and the *Save Medicaid Access and Resources Together (SMART) Act* required a hemophilia utilization review and control program that was initiated in August 2012. The program requires adherence to quality standards for providers that dispense factor, a Standards of Care Agreement (SOCA), dispensing of appropriate quantity to ensure wastage does not occur, prior approval for 30-day monthly supply, assay management, recall protocols, and data collection. Currently 280 patients are enrolled in the HFS Hemophilia Care Program. Approximately 96% are males newborn to 51 years of age and about 4% are females 3 to 40 years of age. At least 90% are Factor 8 deficient with severe Hemophilia A. The rest have Hemophilia B or von Willebrand disease. All clotting factors are covered in the program. The average units and spend per user per month and the average spend per blood factor unit have decreased annually. Total factor spend has decreased from \$43 million in fiscal year 2012 to \$30.5 million in fiscal year 2014. The HFS Hemophilia Care Program has improved patient care and decreased costs due to wastage. Sheri Dolan, BSPHarm, noted the program is “high-touch”. Clients receive factor at least once a month and their compliance is monitored. Mary Lynn Moody, BSPHarm, noted that the program identified and solved improper storage that was contributing to product wastage. Arvin Goyal, MD, questioned whether there was an age cut-off for factor approval and was informed that there is no age cutoff. Patients with coagulation disorders are living longer as improved understanding over the last 20 years provides prophylactic treatment more effectively to prevent bleeding episodes. Patients older than 60 years of age are rare because they were treated in the 1980’s, when transfusion-related infections and blood supply problems were common.

Asthma. Christina Petrykiw, PharmD reviewed progress with the retrospective drug utilization review targeting overutilization of short-acting beta-agonists and underutilization of first-line controller steroid inhalers in pediatric clients who had more than one Emergency Room and medical visit for asthma in fiscal year 2013. Of the 2,868 pediatric clients who had visited the Emergency Room more than once, 2,641 clients had more than one medical visit for asthma and of these, 189 clients were hospitalized for asthma. Of clients who visited the Emergency Room more than once, 81% of clients filled a controller medication, 87% of clients filled quick-relief inhalers, and 78% of clients filled other quick-relief dosage forms. At least 250 pediatric clients filled 8 or more quick-relief inhalers. Of these clients, 30 clients filled 0-2 controller medications, 49 clients filled 3-6 controller medications, 71 clients filled 7-11 controller medications, and 100 filled 12 or more controller medications during fiscal year 2013. In-depth medication profile review for fiscal year 2014 was conducted for the 30 clients who overused quick-relief inhalers and used controller medications minimally. John Tulley, MD, asked if patients filling multiple inhalers were getting them from

10.22.14. Illinois Drug Utilization Review Board Meeting Summary

the same or different physicians. Christina Petrykiw, PharmD, noted that this was not assessed, but can be evaluated for next time. Profile review revealed that quick-relief medications seem to be the primary method of asthma management, with 77% of cases supplemented with oral steroid bursts to manage acute exacerbations. Alternative quick-relief dosage forms are used more than steroid inhalers. At least 20% of clients use products during the fall allergy season exclusively. Approximately 50% of the clients have a spacer Aerochamber-type device, but are not filling steroid inhalers. Medication use also clustered around time of infection treated with anti-infectives in 40% of clients. The EpiPen was used in 23% of clients, signifying concomitant allergies for which quick relief inhalers might also be used. A few client profiles demonstrate multiple voided prescriptions signifying the medications were ordered, but never picked up. Seven of the 30 clients had taken the steroid-containing inhaler Advair when it was preferred, but at time of review five of these clients were no longer filling any steroid inhalers via Medicaid. These clients are priority interventions because despite all providers being contacted when Advair became non-preferred about the need to switch to a different steroid inhaler, this was not accomplished or the clients are receiving sample inhalers and/or paying out-of-pocket for product. There may be patient or caregiver misunderstanding that no Advair coverage means no steroid inhaler coverage as well as patient or caregiver misunderstanding of the role the steroid inhaler plays in asthma management. Although all patients with asthma should be immunized against influenza, none was evident in the claims history, most likely because immunizations are covered by Vaccines for Children programs. One client did fill Tamiflu. Overall steroid inhaler use increased in fiscal year 2014 in 23% of the clients, but beta-agonist nebulization also increased. Montelukast, but not steroid use, increased in two clients. Only one client had filled a peak flow meter. Rachel Caskey, MD, noted this was not surprising since peak flow meter use has decreased after studies did not demonstrate significant asthma improvement in peak flow meter users. The DUR Board members inquired whether inhaler usage also clustered around time of Emergency Room visit or hospitalization. Christina Petrykiw, PharmD, stated that this can be checked, but was not readily apparent from the pharmacy claims data. Provider discussions reveal a need to reiterate that first-line therapy per evidence-based guidelines is a steroid inhaler, where fewer growth-impact concerns exist compared to long-term oral steroid therapy. Lori Wilken, PharmD, noted that in mild persistent asthma, a steroid inhaler may be used only with acute exacerbations due to concerns about growth impact with steroid use in children. Provider outreach should incorporate pharmacy and medical providers. At least 80% of clients are filling their asthma medications with a chain pharmacy (Walgreens, CVS, Target, Walmart) and 17% are filling with independent pharmacies. One client used multiple pharmacies (different chains and independents) to fill their prescriptions. Telephone call-outs to medical providers listed on the last refill of an asthma medication will be conducted next to identify if that provider is primarily responsible for managing the client's asthma, to inform of the clients' overuse of quick-reliever and underuse of controller medications, to determine if the provider is aware of non-adherence with medication use, to inquire about the asthma treatment plan and asthma severity and to confirm the asthma diagnosis. Evaluation can determine if fills are consistent with the treatment plan. Physicians will be asked whether they wish HFS to reach out to the patient with education regarding asthma management. The client's pharmacy may be incorporated to improve asthma medication adherence and check inhaler technique. Anitha Nagelli, PharmD, inquired whether the clients stayed with the same pharmacy. This did occur in the majority of cases. Mary Lynn Moody, BSPHarm, noted that asthma interventions can be a pilot to evaluate use of the local pharmacies and HFS to improve asthma care. After the medical provider telephonic intervention, a fax follow-up will address the Illinois DUR Board asthma initiative, review the pharmacists' treatment recommendations, and provide client-specific asthma-related emergency room, medical, hospitalization, and pharmacy claim history. John Tulley, MD, inquired about situations where only urgent care is being used for managing asthma. The intervention may be able to route the patient to a regular medical provider. Christina Petrykiw, PharmD, asked whether providers of patients who are overusing quick-reliever medications, but filling controller medications monthly should also be targeted. The DUR Board felt that overuse of quick reliever medications still provides an opportunity to improve asthma care in these clients. Anitha Nagelli, PharmD, asked about omalizumab (Xolair) usage. Christina Petrykiw, PharmD, noted that overall few clients were taking Xolair and none of the clients reviewed to date were using it. Rachel Caskey, MD, mentioned several very good Internet videos that demonstrate appropriate inhaler use. Referral to similar smartphone applications would be most successful, particularly if they are in many languages. Rachel Caskey, MD, called for a vote and DUR Board members unanimously approved the provider fax form.

Educational initiatives

2013 ACC/AHA Cholesterol Guidelines. Christina Petrykiw, PharmD, informed DUR Board members that the Medication Review and Academic Detailing pharmacists had identified needed medical provider education regarding the new 2013 cholesterol management guidelines. A guideline summary was posted on the DUR Education Website.

10.22.14. Illinois Drug Utilization Review Board Meeting Summary

Pain management. Christina Petrykiw, PharmD, recommended posting links on the DUR Website to the recently published position paper of the American Academy of Neurology about opioids for chronic noncancer pain because it reinforces the initiatives HFS has undertaken for pain management. Posting a link on the DUR Board page to the Illinois Prescription Monitoring Program (ILPMP) was proposed to facilitate provider enrollment in ILPMP for those accessing the DUR educational materials. Anitha Nagelli, PharmD, asked whether ILPMP showed that a pain management contract was done. Mary Lynn Moody, BSPHarm, explained that ILPMP data is administered by an outside agency that receives submissions of pharmacy claims only. Electronic medical records (EMR) may provide the pain contract as an attachment in the patient's profile. John Tulley, MD, noted that it is not possible to discern what is in an attachment, thus unless opened, it may be missed. Rachel Caskey, MD, called for a vote and the DUR Board members unanimously approved posting links to the educational materials on the DUR Website.

Educating providers about HFS initiatives – MEDI. Mary Lynn Moody, BSPHarm, stated that MEDI educational sessions for pharmacy and medical providers were conducted in southern and central Illinois and two state pharmacy association meetings. Pharmacists trained at Walgreens regional meetings will train additional Walgreens staff. Request submission via MEDI shortens the adjudication process by 4 to 6 hours compared with hotline or fax submission, which require data entry. Anitha Nagelli, PharmD, noted increasing nursing requests for MEDI training, mentioned system improvement since initial launch, asked how approved medication lists are handled and how to determine approval duration for medication lists. Mary Lynn Moody, BSPHarm, noted that nursing staff is usually the primary staff trained in physician practices. Medications submitted on a list are entered individually. Each product receives its own prior authorization number and appropriate prior approval expiration date. Most medications for chronic conditions are approved for a year, unless prior authorization criteria support shorter approval durations. Dates or reminders in the chart can help determine when the list may need to be resubmitted. Approval status and duration can be checked via the hotline, MEDI, and via [online inquiry](#). Christina Petrykiw, PharmD, requested not submitting prior authorization requests for the whole medication list at every clinic visit, since the majority of chronic medications are approved for a year. John Tulley, MD, stated EMR medication lists do not facilitate knowing what was submitted, leading to frequent resubmissions.

Public comments

Allyn Bandel, MedImmune Medical Affairs addressed the pavalizumab (Synagis) prophylaxis guidelines published July 28, 2014 noting that statements about no substantial benefit from Synagis prophylaxis in non-BPD infants gestational ages 29-32 months did not take into account data published in the last 12-24 months in the New England Journal of Medicine and Cochrane reviews. The 2014 Synagis guidelines did not incorporate Institute Of Medicine guideline development recommendations for potential impact on harm from guideline application. Synagis package insert information was reviewed. Ketul Patel, Vertex, offered to address DUR Board member questions regarding Kalydeco. The DUR Board members did not have any questions.

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 10:00 am.

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

Approved February 18, 2015 by the Illinois Drug Utilization Review Board.