

## Drug Utilization Review Board Meeting Summary November 15, 2017

The Drug Utilization Review (DUR) Board met on Wednesday, November 15, 2017, 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; Stacie Laff\*, MD; Anitha Nagelli, PharmD, M.Ed; Bedrija Nikocecic, PharmD; Christopher Schriever, PharmD, MS; John E. Tulley, MD (until 9:30 am).

Illinois Department of Healthcare and Family Services (HFS) Representatives: Donna Clay, BSP Pharm, Prior Authorization, University of Illinois at Chicago (UIC); Jennifer DeWitt\*, BSP Pharm, HFS Bureau of Professional and Ancillary Services (BPAS); Arvind K. Goyal\*, MD, Medical Director, Medical Programs, HFS; Mark Huston\*, Bureau Chief, BPAS; Mary Lynn Moody\*, BSP Pharm, UIC; Zhen Ou, PharmD, UIC; Christina Petrykiw, PharmD, CDE, UIC; Jonathan Samardzich, PharmD, UIC; Linda Schuh\*, BSP Pharm, BPAS; Patricia Steward\*, BSP Pharm, BPAS.

Interested parties: Gerald Cavanagh, PharmD candidate, UIC College of Pharmacy (COP); Michelle Gonzales; Randy Huetsch, Kite; Michael LaFond, Abbvie; Danielle Leonard, Johnson & Johnson; Marcia Luckett, Genentech; Karen Malamut, DO, Merck; Rich Maloy, Braeburn Pharmaceuticals; Kelly Maynard; Jenn McNary; Donna Osterlund, Genzyme; Brenda Nunnally, AstraZeneca; David Oh, PharmD candidate, COP; Janet Ritter, Genzyme; Chris Stanfield, Supernus; Awni Swais, Shire; Dom Spatalisano, Ipsen Biopharmaceuticals; Tom Theiss, Ipsen Biopharmaceuticals.

\*Attendance via teleconference

**Call to Order.** Rachel Caskey, MD, called the meeting to order on November 15, 2017 at 8:34 am.

**Agenda, conflict of interest review, and approval of September 20, 2017 meeting minutes.** Illinois DUR Board members had no changes to the September 20, 2017 minutes or the November 15, 2017 agenda. John Tulley, MD, made a motion, seconded by Christopher Schriever, PharmD, MS, and the DUR Board unanimously approved the November 15, 2017 minutes.

**DUR Board meeting schedule 2018.** Christina Petrykiw, PharmD, reviewed the DUR Board schedule for 2018. Rachel Caskey, MD, made a motion, seconded by John Tulley, MD and the DUR Board unanimously approved the 2018 DUR Board meeting schedule. The schedule will be posted on the HFS DUR Board Webpage.

**Meeting chairperson and vice-chairperson.** Christina Petrykiw, PharmD, explained that the DUR Board year parallels the federal fiscal year from October 1<sup>st</sup> to September 30<sup>th</sup> of the following year. Two DUR Board members indicated interest in serving a leadership role on the DUR Board – Stacie Laff, MD as chairperson and Christopher Schriever, PharmD as vice-chairperson. John Tulley, MD made a motion, seconded by Bedrija Nikocecic, PharmD, and the DUR Board members unanimously voted in the new chairperson and vice-chairperson.

### Prospective Drug Utilization Review

**Preferred Drug List (PDL) status updates.** Christina Petrykiw, PharmD, informed DUR Board members about PDL changes effective October 1, 2017. Vyvanse became a preferred long-acting medication for the treatment of attention deficit disorder. The PDL status of all currently available long-acting stimulants was reviewed. New preferred medications for diabetes now include Januvia (sitagliptin), Victoza (liraglutide), Invokana (canagliflozin), and Jardiance (empagliflozin). Current status of all available DPP-4 inhibitors, GLP-1 receptor antagonists, and SGLT2 inhibitors was reviewed. Dr. Goyal noted that PDL status of medications is important as HFS moves to a single PDL for all Medicaid participants effective July 1, 2018.

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**Atopic dermatitis (Eucrisa, Dupixent).** Christina Petrykiw, PharmD, reviewed the pathophysiology, symptoms, diagnosis, and guideline-based management of atopic dermatitis (AD), which primarily affects children and frequently resolves by adulthood. Currently there is no cure for atopic dermatitis. Management targets symptoms, inhibition of immune-mediated inflammatory effects, and prevention of exacerbation or flares. Non-pharmacologic methods are the mainstay of treatment. Pharmacologic therapy is added when the non-pharmacologic methods are insufficient. First-line pharmacologic therapy is topical steroids. Dermatologist referral is recommended in cases of recurrent skin infections, extensive or severe disease, and poor symptom control with topical steroids. Step therapy depends on severity of AD. In addition to topical steroids, mild-moderate AD is treated with topical calcineurin inhibitor pimecrolimus (Elidel) cream and then the topical phosphodiesterase-4 inhibitor crisaborole (Eucrisa). Moderate to severe AD is treated with the topical calcineurin inhibitor tacrolimus (Protopic) ointment, followed by systemic oral immunosuppressive agents (cyclosporine, azathioprine, methotrexate, mycophenolate mofetil) and the systemic injectable interleukin-4 receptor alpha antagonist dupilumab (Dupixent). An overview of crisaborole and dupilumab mechanisms, dosage forms, administration, adverse effects, drug interactions, and clinical trial outcomes was presented. Positive outcomes were achieved in less than 40% of patients treated with these medications and depending on the medication compared, in 8% to 25% of placebo-treated patients. Zhen Ou, PharmD, reviewed HFS initial and renewal prior authorization criteria and limits for medications used in the treatment of AD. Prior authorization medical directors, as well as outside allergists and dermatologists had reviewed and provided input on the criteria. Treatment with at least two trials of topical steroids of at least medium to high potency for a sufficient duration is expected before advancing therapy. Bedrija Nikocecic, PharmD, asked whether patients needed to use pimecrolimus, then tacrolimus, before progressing to other medications. Donna Clay, BSP Pharm, noted case-by-case evaluation is done to ensure use of appropriate therapy for the severity of AD and that at least one calcineurin inhibitor is used before therapy is augmented with crisaborole or systemic agents. Stacie Laff, MD, voiced concern that pediatricians were not included among the specialists required as prescribers for crisaborole, despite treating AD in at least 50% of their patients. Patients can frequently present with more severe AD, including bleeding excoriated lesions requiring stepped up therapy. It can take 6 months to get an appointment with an allergist, dermatologist, or immunologist in rural areas so it should not be the sole denial reason. Christina Petrykiw, PharmD, reminded everyone that the guidelines recommend dermatologist intervention for progressive AD. Christopher Schriever, PharmD, suggested pediatricians with appropriate training be included. Rachel Caskey, MD noted that appropriate “training” would have to be defined. Arvin Goyal, MD, Medical Director, Medical Programs, HFS, mentioned that all pediatricians and family medicine practitioners undergo required dermatology rotations within their residencies. John Tulley, MD, noted that when AD severity is increased and first-line therapy is insufficient, that a specialist consult is helpful to ensure that the correct dermatologic condition is being treated. Stacie Laff, MD, highlighted additional issues in children including therapy non-adherence, insufficient patient and caregiver education about amount of non-pharmacologic moisturizer needed, as well as caregiver concerns about steroid absorption and impact on growth. Pediatricians refer more difficult cases. Rachel Caskey, MD, recommended use of the prior authorization criteria for Eucrisa and Dupixent, keeping in mind, that the prescriber criterion will be considered on a case-by-case basis. The DUR Board members agreed with this recommendation. Mark Huston, Bureau Chief, BPAS, suggested an internal re-review of the criteria based on DUR Board member input. The DUR Board members confirmed that the only criterion that may need to be reviewed is the type of prescriber allowed for use of Eucrisa.

**Benzodiazepine prospective edits.** Christina Petrykiw, PharmD, acknowledged the efficacy of short-term benzodiazepine use for acute exacerbation of anxiety/panic disorder symptoms and highlighted benzodiazepines’ potential for physical and psychological dependence that can occur within a short time period after therapy initiation. Food and Drug Administration (FDA) warnings about negative effects on respiration in patients with certain respiratory conditions or when used concomitantly with opioids/medications that are central nervous system depressants were reviewed. In cases of unavoidable concomitant use, the FDA recommends limiting dosages and durations of medications to the minimum possible to achieve desired effects. The age breakdown of benzodiazepine use in the HFS Fee-for-Service population has been relatively consistent since calendar year 2014. Highest use is in participants 19 to 49 years of age. Mechanisms that may be used to ensure appropriate medication use and previous HFS and DUR Board benzodiazepine recommendations were reviewed. The DUR Board members were asked to comment on the following potential prospective edits: decreasing allowed monthly quantity to 90 from 120 for all immediate-release benzodiazepines; requiring prior approval for all or only select benzodiazepines (i.e., alprazolam); not allowing use if contraindicated/non-recommended medical conditions or concomitant medications present; continuation of current duplicate therapy edits, prescriber outreach for participants with long-term use, and seizure diagnosis checks for clonazepam; ensuring age limits appropriate per package insert/indication; short duration of

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approval; and requiring signed prescriber-patient benzodiazepine informed consent. Stacie Laff, MD, recommended limiting benzodiazepines to adults only and potentially requiring neurologist-prescribers for pediatric patients to stem inappropriate and indiscriminate prescribing in children. John Tulley, MD, noted that inappropriate benzodiazepine use in settings of concomitant opioids and skeletal muscle relaxants that can have potentially fatal consequences, should be a priority. The DUR Board members recommended allowing acute use and requiring prior authorization with the second fill. Arvin Goyal, MD, Medical Director, Medical Programs, HFS, noted that appropriate, safe use is applicable to all benzodiazepines and potentially accomplished most effectively with a prior authorization requirement for the whole drug class. Donna Clay, BPharm, noted that staff implications due to request volume will need to be evaluated by HFS. Currently benzodiazepine requests are received for duplicate therapy, monthly quantities greater than 120, and Four Prescription Policy. The DUR Board members felt that for chronic benzodiazepine therapy, HFS participants should be limited to one prescriber and pharmacy, with required Illinois Prescription Monitoring Program checks, and lower quantities of 90 or 120, particularly if concomitant opioid therapy was present. There was no desire to precipitate withdrawal and there is a need to taper, implement other therapies, and prescriber training. Bedrija Nikocecic, PharmD, suggested a grace period before implementation, staggered implementation, or grandfathering of current chronic users. Anitha Nagelli, PharmD, noted that a transitional fill of at least 30 days could allow for prescriber notification and taper initiation. Bedrija Nikocecic, PharmD, noted that since transitional fills are basically approvals and the claim pays, messages about temporary aspect of the approval will be missed. Messages are primarily read when the claim rejects. Anitha Nagelli, PharmD, asked whether the new PBMS system had bidirectional capability, where the pharmacist could override the rejection, which would facilitate a transitional fill. A 14-day approval would allow for the claim to reject at 30 days. Alternatively, allowing a 72-hour emergency fill for the first request can allow medication for an acute event. Christina Petrykiw, PharmD, asked DUR Board members to clarify duration of a first fill for new benzodiazepine patient and to define a second or transitional fill. Currently prescribers for benzodiazepine requests within the Four Prescription Limit receive a letter and that can be augmented with information about transitional fill. Arvin Goyal, MD, noted given dependence can occur quickly, that it would be prudent to make the first fill short, for example 1 week, and then with second fill require prior authorization for all benzodiazepines after a seizure check for clonazepam. Mark Huston, Bureau Chief, BPAS, noted that a prior authorization requirement after the first fill or edits requiring duration limits will require PBM system coding. Those types of edits would be incorporated into the vendor's coding requests timeline and will take longer to accomplish. Christopher Schriever, PharmD, noted that if first-line therapy with a selective serotonin reuptake inhibitor (SSRI) or a serotonin and norepinephrine reuptake inhibitor (SNRI) is started at the time of the first benzodiazepine prescription, then it will take time (up to 8 weeks) to get to a therapeutic level of the SSRI-SNRI. The first benzodiazepine fill duration would have to be longer than a week to ensure symptoms are being managed as first-line therapy achieves therapeutic levels. Bedrija Nikocecic, PharmD, agreed and noted that within the retail setting 1 week may not be sufficient to submit a prior authorization request with prescriber input and receive a response – 2 weeks would be more realistic and more helpful in treating an acute event. The DUR Board members noted that greatest need would be to prevent dependence in a new start with shorter approval windows, and different duration periods would be needed to facilitate transitional fills and tapers in chronic benzodiazepine users. Arvin Goyal, MD, reiterated that clonazepam should be limited to the seizure indication. Use of short-acting benzodiazepines stimulates the reward system so even lower doses can cause dependence. Applying individual edits produces a piecemeal approach and may not facilitate sufficient patient and prescriber education. Christopher Schriever, PharmD, made a motion to require prior authorization for all benzodiazepines for all ages after the second fill. The first allowed fill for acute management should be limited to 14 days (2 weeks) with a maximum of 60 tablets. If the participant for whom clonazepam is requested does not have a seizure diagnosis, then prior authorization should be required for clonazepam since usage shift to clonazepam has started to become evident. All other current prospective benzodiazepine edits should remain in place. The DUR Board members unanimously approved this motion and requested presentation of a benzodiazepine plan at the next meeting.

### **Retrospective Drug Utilization Review**

**Medicaid Prescriber Narcotic Prescribing.** Christina Petrykiw, PharmD, asked DUR Board members for input regarding reviewing narcotic prescribing at the prescriber rather than individual patient level. The methodology used for the Medicare Part D Prescribing Mapping Tool was reviewed. The tool helps determine opioid prescribing rates at state, county, zip code and individual prescriber levels. It can also be used for peer comparisons, which has helped improve prescribing, even if it is for a transient time. Use of a similar methodology could help determine which HFS prescribers to target with education for appropriate opioid prescribing. Prescribers would receive information about their opioid prescribing rate and potential peer comparisons along with education for improving prescribing. The DUR

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Board members noted that this may be useful if used to provide a broad comparison of prescribing feedback and if used to educate the prescriber. Stacie Laff, MD, asked for more information regarding the prescriber letter. Rachel Caskey, MD, noted that this may be useful if it does not compromise staff resources. Christina Petrykiw, PharmD, noted that a prototype letter would be provided to DUR Board members for review, but at this time feedback was needed regarding this type of prescriber evaluation. Currently individual patient letters are sent to prescribers. Resource use will be evaluated as HFS conducts required review related to appropriate prescribing.

### **Education**

**Benzodiazepine education.** Christina Petrykiw, PharmD, asked DUR Board members about benzodiazepine-related education suggestions after their review of initiatives from New York City, the state of Pennsylvania, and the Veterans Administration (VA). Rachel Caskey, MD, made a motion, seconded by Dr. Laff to post the links to the benzodiazepine prescriber materials from all of these initiatives on the DUR Education Web page. The DUR Board members unanimously agreed. Linking to already available materials was deemed effective use of staff resources. Sending prescribers faxes, even if patient specific, is more passive and often any incorporated education is not seen by the prescriber inundated with faxes. Sending literature may not be worth the time and would not be as impactful. Christopher Schriever, PharmD, noted that targeting myths of prescribing, i.e., dependence relationship with pharmacokinetic profile of benzodiazepine is potentially useful, if substantiated with review of medication pharmacokinetics and pharmacologic effects. Stacie Laff, MD, suggested Webinars or interactive Web-based education which may be more effective than faxes, particularly if continuing education credit can be offered. Rachel Caskey, MD, suggested identifying Internet-based educational resources that discuss basic benzodiazepine information, which are plentiful, rather than creating them. Anitha Nagelli, PharmD, noted that incorporating Illinois specific data would garnish the most attention rather than generic education about benzodiazepines. Presentations at state or regional pharmacy and prescriber meetings that incorporate a state-specific, HFS focused update related to appropriate medication use, something similar to a roving grand rounds, would be useful. Christina Petrykiw, PharmD, noted that HFS booths at state pharmacy association meetings have provided materials regarding appropriate prescribing of medications and computers were used to teach prescribers how to enroll in Impact. Bedrija Nikocecic, PharmD noted that an educational article regarding appropriate benzodiazepine prescribing in the Pharmacist's Letter, a frequently used medication information resource, would effectively reach many practitioners. The Illinois Department of Financial and Professional Regulation of Pharmacy Newsletter, which is no longer mailed to the pharmacist's home, is not used as frequently. Prescribers do not have a similar Illinois newsletter. Arvin Goyal, MD informed DUR Board members that the Governor's Task Force is working with the Department of Professional Regulation to address opioid prescribing and dispensing guidelines. Additionally, the Illinois Department of Human Services Division of Alcoholism and Substance Abuse (DASA) worked with a contractor to create a public education campaign regarding appropriate opioid use. The campaign will be rolled out after the Task Force completes its review.

### **Future agenda items.**

Dr. Caskey asked DUR Board members for additional medication use issues HFS should be evaluating. Bedrija Nikocecic, PharmD asked about coverage for the new shingle vaccine for adults 50 years of age and older recommended by the Centers for Disease Control and Prevention (CDC). Patty Steward, BSPharm noted that CDC-recommended vaccines are covered. Additional issues identified can be forwarded to Christina Petrykiw, PharmD,

**Public comments.** Dr. Caskey invited attendees wishing to speak to provide comments. Kelly Maynard, national advocate from Little Hercules Foundation for Duchenne Muscular Dystrophy in Ohio, spoke about the impact of the condition on children/families and the role Exondys can play in potentially delaying the progression of the disease. Jenn McNary, national advocate from Boston for children/families impacted by Duchenne Muscular Dystrophy, noted the positive role Exondys had for children and commented about the lack of public discourse about Exondys availability for Illinois Medicaid participants. She urged HFS to put in place a coverage policy for Exondys. Michelle Gonzales highlighted the difficulties children have with worsening Duchenne Muscular Dystrophy while Exondys prior authorization requests remain denied.

**Adjournment.** Dr. Caskey adjourned the DUR Board meeting at 10:30 am.

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

**Approved February 14, 2018 by the Illinois Drug Utilization Review Board.**