Drug Utilization Review (DUR) Board
Meeting Summary
March 21, 2013

Agenda and Introduction:

The Drug Utilization Review Board met on Thursday, March 21, 2013 from 9:00 A.M. to 4:00 P.M., in Meeting Room 6, Concourse, Empire State Plaza, Albany, New York.

A. Background Materials Provided:

The DUR Board members were provided copies of materials submitted by interested parties in advance of the meeting.

B. Public Comment Period:

The following speakers provided comments to the DUR Board:

Murray, Stephen, PharmD, MBA, Senior CNS Medical Science Liaison, Otsuka America Pharmaceutical, Inc., Rockville, MD

C. Key Issues Presented by Interested Parties and Discussed by the DUR Board during the Public Comment Period:

Testimony provided a general overview of Abilify (aripiprazole) including indications, mechanism of action and safety information.

D. Presentations, Discussions, and Program Updates:

The following speakers presented to the DUR Board:

- Coe, Holly, PharmD, Clinical Assistant Professor, School of Pharmacy and Pharmaceutical Sciences, State University of New York at Buffalo
- Correia, Robert, PharmD, New York State Department of Health, Office of Health Insurance Programs
- Donohue, Connie, AuD, Assistant Director of Policy Analysis and Development, New York State Department of Health, Office of Health Insurance Programs
- Elkind, Janet Z., Deputy Director, Division of Program Development and Management, Office of Health Insurance Programs
- Hong, Irene, PharmD, Clinical Assistant Professor, School of Pharmacy and Pharmaceutical Sciences, State University of New York at Buffalo
- Khadem, Tina, PharmD, Outcomes Research Fellow, School of Pharmacy and Pharmaceutical Sciences, State University of New York at Buffalo
- Lambert, Drew, PharmD, School of Pharmacy and Pharmaceutical Sciences, State University of New York at Buffalo
- Merola, Anthony, RPh, MBA, New York State Department of Health, Office of Health Insurance Programs

- Naioti, John F., Jr., RPh, New York State Department of Health, Office of Health Insurance Programs
- O'Leary, Terence J., Director, Bureau of Narcotic Enforcement

American Drug Utilization Review Society

Mr. Naioti presented an update on the American Drug Utilization Review Society (ADURS) Conference. ADURS is a national, non-profit organization of Medicaid drug utilization review programs from each State and the District of Columbia. The annual conference promotes collaboration and sharing of information, development of skills, and provides support and training for members.

Executive Budget Proposals

Ms. Elkind presented an update on the New York State Medicaid Executive Budget Proposals. The information presented was specific to pharmacy budget initiatives for the Medicaid program. Topics presented included prescriber prevails provision, pharmacy reimbursement, supplemental rebates, and early refill edits. Modification of the P&T Committee meeting summary postings requirements and the concept of merging the P&T Committee with the Drug Utilization Review (DUR) Board were also discussed. At the time of the meeting, no official action had been taken on these budget proposals.

Pharmacy Management Collaborative

Mr. Merola presented an update of the Pharmacy Management Collaborative. The Pharmacy Management Collaborative will work through teams representing NYSDOH, SUNY, and the managed care plans. The intent is to evaluate services for beneficiaries within both managed care and fee-for-service populations, and to work toward a common goal that would ensure improved quality and promote uniformity in the approach of identifying appropriate practice and drug utilization guidelines.

Medicaid Evidence Based Benefit Review Committee

Dr. Donohue presented an update of the Medicaid Evidence Based Benefit Review Committee. The Committee consists of internal and external workgroups engaged in evidence informed policy making. An overview of some of the projects of the Medicaid Redesign Team (MRT) was also discussed. The Medicaid Redesign Team focuses on a formal process involving consistency and transparency, and utilizes specific analysis in order to make evidence-based benefit decisions.

Medicaid Fee-for-Service Claims System Edits

Dr. Khadem presented an update of the Medicaid Claim System Edits for the fee-for-service pharmacy program. The update included utilization data of five different topics. Fee-for-service Medicaid paid for pharmacy claims until October 2011, at which time managed care began to pay for the majority (approximately 75%) of these claims. The measurement of utilization after implementation of point of service edits became complicated as a result of the transition to managed care, the introduction of some new generics in the marketplace, and the change of some medications from preferred to non-preferred in the Preferred Drug List.

Prescriber Education Program

Drs. Hong and Lehmann presented program updates with regard to the Prescriber Education Program (PEP). The purpose of the program is to improve patient care by providing physicians with the latest unbiased information in regards to best practices and therapeutics in order to make informed decisions. The focus of this update was specific to pain management in low back pain and the utilization of short acting opioids, specifically oxycodone and oxycodone/APAP. The DURB has recommended limits on length of treatment without prior authorization for short acting opioids (excluding tramadol) for beneficiaries without a diagnosis of cancer or sickle cell disease. Medicaid claims data indicated high utilization of oxycodone and oxycodone/APAP. Prescriber information indicates that a small number of prescribers within New York State are responsible for a large portion of the prescribing of oxycodone within the Medicaid program. The plan discussed was to integrate informational interventions while optimizing pharmacotherapy options for non-cancer related mechanical low back pain. Face-to-face outreach sessions, education sessions, and dissemination of a white paper were discussed as targeted interventions in address utilization issues.

Long-Acting Beta-2 Agonists

Dr. Coe presented the long-acting beta-2 agonists utilization review. The DUR Board was provided with a general overview of the class, including indications, accepted uses, and clinical considerations based on asthma and COPD guidelines. The Board was also provided with NYS Medicaid claims utilization information including average cost of therapy, units being dispensed, and utilization based on age and diagnosis.

I-STOP (Internet System for Tracking Over-Prescribing Act)

Mr. O'Leary presented an update of the Internet System for Tracking Over-Prescribing Act (I-STOP) and recent changes to the New York State Controlled Substance Act. Mr. O'Leary presented information pertaining to the Prescription Monitoring Program that included data to support the program's validity. He discussed the web-based site that prescribers will be required to consult in most instances beginning August 27, 2013. Mr. O'Leary also discussed electronic prescribing as part of the public health law, and the recent changes to controlled substance schedules for specific medications including hydrocodone and tramadol. Mr. O'Leary also outlined a statewide program for the safe disposal of controlled substances, including drop-off sites in select counties across New York State.

Second Generation Antipsychotics in Pediatrics

Dr. Lambert presented the second-generation antipsychotics in pediatrics utilization review. The DUR Board was provided with a general overview of the drug class, including indications, accepted uses, and relevant safety information. Utilization data from NYS Medicaid claims was provided to the Board, including utilization as it pertains to drug, approved and unsupported diagnosis and beneficiary age.

Dronabinol

Dr. Hong presented the dronabinol utilization review. The DUR Board was provided with a general overview of the medication, including indications, accepted uses, and clinical considerations based on multiple studies. The Board considered utilization of this medication, especially as pertains to its place in therapy relative to other medications such as megestrol acetate and other NYS Medicaid preferred anti-emetic medications. NYS Medicaid claims information was evaluated considering cost, diagnosis, and prior therapy.

Topiramate

Dr. Hong presented the Topiramate utilization review. The DUR Board was provided with a general overview of the medication, including indications, supported uses, and clinical considerations. The Board was also provided with NYS Medicaid claims information including utilization based upon diagnosis.

E. DUR Board Discussion

The DUR Board discussed long-acting beta-2 agonist utilization relating to claims greater than 60 units. Concerns discussed included the possibility of claims being filled for larger than expected quantities, possibly due to beneficiaries' symptoms not controlled and requiring above average amounts of these medications. Board discussion included comparisons in therapy between Advair HFA® and the Advair Diskus®. Only the HFA formulation of Advair can be used with a spacer. While the FDA-approved age limit for the Advair HFA® inhaler is 12 years or older, it was considered that the spacer may allow for better asthma control compared to the diskus. There was discussion of the possibility of the approved age for the HFA inhaler being changed to allow for its use in younger pediatric patients.

The DUR Board discussed second-generation antipsychotics utilization data within the pediatric population including the current need to identify prescribers by specialty. Access to physician psychiatric care for children, prescribing by general practitioners, and determination of therapy for beneficiaries were discussed. Access to care subsequent to a prior authorization requirement was discussed, as well as the concept of behavioral therapy management to be used in conjunction with these agents. Extensive deliberation occurred during the consideration of minimum age of use.

The DUR Board discussed the efficacy and cost considerations of dronabinol, and the relative cost and efficacy of alternative therapies.

The DUR Board discussed topiramate utilization for chronic pain in adult medicine, including that related to diabetic neuropathy, migraine prophylaxis, and low back pain. The Board considered utilization in chronic pain conditions, noting that topiramate in low doses can be well tolerated. Discussion involved topiramate use in place of a tricyclic antidepressant or other agents such gabapentin and pregabalin. Discussion involved use of tricyclic antidepressants and/or antiepileptic medications for chronic treatment of these conditions. The bioavailability of Topamax and generic topiramate was discussed. The Board discussed the impact of prospective DUR editing for diagnoses including epilepsy, migraine prophylaxis, chronic pain and psychiatric disorders.

F. DUR Board Action

Long-Acting Beta-2 Agonists

The Board took the following actions regarding Long-Acting Beta-2 Agonists:

1. Quantity limits as follows:

Medication	Maximum Units per 30 days
Arformoterol (Brovana®)	60 units (or 1 carton of 60 vials or 120 mL)
Formoterol powder (Foradil®)	60 units (or 1 box of 60 unit dose capsules)
Formoterol solution (Perforomist®)	60 units (or 1 carton of 60 vials or 120 mL)
Indacaterol (Arcapta™)	30 units (or 1 box of 30 unit dose capsules)
Salmeterol (Serevent®)	1 diskus (or 60 blisters)
Budesonide/formoterol (Symbicort®)	1 inhaler/diskus
Fluticasone/salmeterol (Advair HFA®)	1 inhaler/diskus
Fluticasone/salmeterol (Advair Diskus®)	1 inhaler/diskus
Mometasone/formoterol (Dulera®)	1 inhaler/diskus

2. Prospective DUR edit for all new long-acting beta agonist prescriptions for beneficiaries under FDA or compendia supported age as indicated below. Clinical Call Center must be contacted to override edit. Electronic bypass for established therapy identified in the claims system.

Medication	FDA/Compendia Supported Age
Arformoterol (Brovana®)	≥ 18 years
Formoterol powder (Foradil®)	≥ 5 years
Formoterol solution (Perforomist®)	≥18 years
Indacaterol (Arcapta™)	≥18 years
Salmeterol (Serevent®)	≥4 years
Budesonide/formoterol (Symbicort®)	≥12 years
Fluticasone/salmeterol (Advair HFA®)	≥12 years
Fluticasone/salmeterol (Advair Diskus®)	≥ 4 years
Mometasone/formoterol (Dulera®)	≥12 years

Second Generation Antipsychotics in Children

The Board took the following action(s) regarding the use of second generation antipsychotics in children:

1. Prospective DUR edit for the initial prescription for beneficiaries younger than the drug-specific minimum age as indicated below. Clinical Call Center must be contacted to override edit. Electronic bypass for these beneficiaries for established therapy.

Medication	Minimum Age
Aripiprazole (Abilify®)	6
Asenapine (Saphris®)	18
Clozapine (Clozaril®, Fazaclo®)	12
Iloperidone (Fanapt®)	18
Lurasidone HCl (Latuda®)	18
Olanzapine (Zyprexa®)	10
Olanzapine/Fluoxetine (Symbyax®)	18
Paliperidone (Invega®)	12
Quetiapine Fum. (Seroquel®)	10
Risperidone (Risperdal®)	5
Ziprasidone HCl (Geodon®)	18

2. Confirm diagnosis for the initial prescription for beneficiaries between minimum age as indicated above and 18 years of age. Electronic bypass for these beneficiaries for established therapy or any indication supported for second-generation antipsychotics for pediatric use.

Dronabinol (Marinol)

The Board took the following action(s) regarding dronabinol (Marinol®):

1. Confirm diagnosis for Medicaid covered uses as follows:
    - HIV/AIDS or Cancer and eating disorder
    - Cancer and nausea/vomiting

    a. Step therapy for beneficiaries with HIV/AIDS, or cancer, AND eating disorder: trial with megestrol acetate suspension prior to dronabinol

    b. Step therapy for beneficiaries with diagnosis of cancer and nausea/vomiting: trial with a NYS Medicaid-preferred 5-HT_3 receptor antagonist prior to dronabinol

Electronic bypass for covered diagnosis and prior utilization of a first line agent as identified in the claims system.

Topiramate

The Board took the following action(s) regarding the use of topiramate:

1. Confirm diagnosis to prevent reimbursement for Medicaid excluded uses. Electronic bypass for covered diagnosis identified in the claims system.

The meeting adjourned at 4:00 P.M.

Meeting Summary Posted 4/23/2013