

Drug Utilization Review (DUR) Board Meeting Summary – March 10, 2011

Agenda and Introduction

The Drug Utilization Review Board met on Thursday, March 10, 2011 from 9:00 A.M. to 4:30 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:

1. Dube, Christine, Pharm D, Director, Medical Sciences, MedImmune LLC, Gaithersburg, MD

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

Respiratory Syncytial Virus (RSV) Treatment Guidelines:
Testimony addressed concerns with the differences in the risk factors and age of use published in the new guidelines.

D. Presentations and Discussions:

The following speakers presented to the DUR Board:

1. Figge, James, MD, Medical Director, Office of Health Insurance Programs, New York State Department of Health
2. McNamara, Daniel, RPh, Medicaid Pharmacy Program, Office of Health Insurance Programs, New York State Department of Health
3. Rogler, Barbara, Pharm D, MS, Magellan Medicaid Administration
4. Toohey, Monica, RPh, Medicaid Pharmacy Program, Office of Health Insurance Programs, New York State Department of Health
5. Doloresco, Fred, Pharm D, Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
6. Wrobel, Mark, Pharm D, Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
7. Hong, Irene, Pharm D, Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
8. Catanzaro, Linda, Pharm D, Clinical Assistant Professor Director, Pharmacotherapy Information Center Chair, HIV Continuing Education Programs, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
9. Fominaya, Cory, Pharm D, Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo

10. Lehmann, David, MD, Pharm D, Professor of Medicine and Pharmacology, State University of New York Upstate Medical University

Antibiotics Miscellaneous (extended-release amoxicillin and delayed-release doxycycline)
Dr. Fominaya presented the extended-release amoxicillin utilization review. The DUR Board was provided with a general overview of extended-release amoxicillin including the indications, accepted uses and clinical considerations. The Board was also provided with NYS Medicaid claim utilization information, including quantity per claim, frequency of refills, and the availability of more cost effective products of equal efficacy.

Dr. Fominaya presented the delayed-release doxycycline utilization review. The DUR Board was provided with a general overview of delayed-release doxycycline including the indications, accepted uses and clinical considerations. The Board was also provided with NYS Medicaid claim utilization information, including quantity per claim, frequency of refills, and the availability of more cost effective products of equal efficacy.

Non-Benzodiazepine Sedative Hypnotics

Dr. Wrobel and Dr. Doloresco presented the Non-Benzodiazepine Sedative Hypnotics utilization review. The DUR Board was provided with a general overview of the drug class including the indications, accepted uses and clinical considerations. The Board was also provided with NYS Medicaid claims utilization information including quantity dispensed, frequency of dispensing, duration of therapy, and the association with additional factors including potential over-utilization and misuse.

Central Nervous System (CNS) Stimulants

Dr. Hong and Dr. Doloresco presented the CNS Stimulants utilization review. The DUR Board was provided with a general overview of the drug class including the indications, accepted uses and clinical considerations associated with the Attention Deficit Disorder and sleep disorders. The Board was also provided with NYS Medicaid claims utilization information specifically related to age, quantity dispensed, frequency of dispensing, duration of therapy, and the association with additional factors including potential over-utilization and misuse.

Anabolic Steroids

Dr. Catanzaro and Dr. Doloresco presented the Anabolic Steroid utilization review. The DUR Board was provided with a general overview of the drug class including the indications, accepted uses and clinical considerations associated with hypogonadism. The Board was also provided with NYS Medicaid claim utilization information, including quantity per claim, frequency of refills, and the association with additional factors including potential over-utilization and misuse.

Respiratory Syncytial Virus (RSV) Treatment Guidelines

Dr. Figge presented an overview of the New York State Medicaid guidelines for palivizumab utilization for the 2011-2012 RSV season. The guidelines included information regarding groups at risk, seasonal dose limits, and additional criteria including chronological age.

Prescriber Education Program (PEP)

Dr. Lehmann and Dr. Figge presented the Prescriber Education Program (PEP) update. Dr. Lehmann provided the Board with information regarding PEP personnel updates, including the status of current and imminent planned statewide geographical rollouts for the academic educators. The Board was also updated on strategies to strengthen ties between individual prescribers, how the Drug Information Resource Center will be integrated into the PEP, and a status update of the multiple modules. Dr. Figge presented the Board with the clinical guidance document for the module relevant to treating type II diabetes, titled "Treating Type 2 Diabetes Mellitus: a New York State Medicaid Clinical Guidance Document".

DUR Retrospective Analysis

Mr. McNamara and Dr. Rogler provided a DUR retrospective report. Mr. McNamara provided an

overview of the Clinical Drug Review Program (CDRP) drugs and drug classes that were previously addressed by the DUR Board and referred to the Pharmacy and Therapeutics (P&T) Committee for further evaluation. The DUR Board was provided a brief overview of the P&T Committee's recommendations in relation to the Commissioner's final determinations and implementation timelines. Dr. Rogler provided a post implementation analysis of the claims volume and prior authorization requests of Xyrem, Human Growth Hormones, and Topical Immunomodulators.

DUR Website Enhancements

Ms. Toohey presented the Board with a brief overview of DUR website enhancements. The Board was provided screenshots of the website home page and links. The Board was also provided with information on future DUR links to be included on the Preferred Drug List.

E. DUR Board Discussion

The DUR Board discussed utilization of extended-release amoxicillin in relation to the lone indication for the treatment of *S. Pyogenes* and initial use of equipotent, more cost effective non-extended-release amoxicillin and/or penicillin. The Board also discussed the need to ensure appropriate duration of therapy when extended-release amoxicillin is prescribed.

The DUR Board discussed utilization of delayed-release doxycycline in relation to initial use of equipotent, more cost effective non-delayed-release doxycycline. The Board also discussed quantity, frequency and duration limits for the treatment of acute infections with delayed-release doxycycline.

The DUR Board discussed utilization of non-benzodiazepine sedative hypnotics in relation to quantity and duration limits based on Food and Drug Administration (FDA) labeling and use supported by Compendia. The Board also discussed distributing education materials to providers regarding safety concerns related to proper monitoring of patients initiating treatment with these medications.

The DUR Board discussed the use of CNS stimulants in relation to the use within evidence-based daily dosages and frequency as determined by (FDA) labeling. The Board also discussed issues with CNS stimulants based on age, safety and public health concerns, potential for illicit use and diversion, and use inconsistent with approved indications.

The DUR Board discussed the use of anabolic steroids in relation to duration limits based on documented diagnosis and approved FDA labeled daily dosing. The Board also discussed the history and potential for abuse, diversion, and illegal use, as well as use inconsistent with approved indications and documented safety and public health concerns pertaining to anabolic steroids.

G. DUR Board Action:

Miscellaneous Antibiotics

The DUR Board took the following action(s) regarding extended-release amoxicillin:

- Step therapy will be applied for Moxatag® (extended-release amoxicillin) for patients that have not attempted to use a more cost effective immediate-release amoxicillin first.
- Quantity limit: 10 tablets

The DUR Board took the following action(s) regarding doxycycline delayed-release:

- Step therapy will be applied for delayed-release doxycycline for patients that have not attempted to use a more cost effective immediate-release doxycycline first.
- Quantity limit of ≤ 28 units

Non-Benzodiazepine Sedative Hypnotics (NBSHs)

The DUR Board took the following action(s) regarding Non-Benzodiazepine Sedative Hypnotics:

- Duration limit equivalent to the maximum recommended duration per Compendia sources:
 - 360 days for immediate-release zolpidem products
 - 180 days for eszopiclone and ramelteon products
 - 168 days for extended-release zolpidem products
 - 30 days for zaleplon products
- Frequency limit, based on recommended maximum daily doses:
 - 30 dosage units per fill/1 dosage unit per day/30 days for non-zaleplon-containing NBSHs
 - 60 dosage units per fill/2 dosage units per day/30 days for zaleplon-containing NBSHs
 - A first-fill duration and quantity limit for each NBSH of 10 days/10 dosage units for patients naïve to the prescribed NBSH (exception for zaleplon-containing products 10 days/20 dosage units)
- A letter to providers regarding use of NBSHs pertaining to first-fill duration and the maximum applicable quantity and duration limits.

Central Nervous System Stimulants

The DUR Board took the following action(s) regarding CNS stimulants:

- Quantity limits based on a daily dosage as determined by FDA labeling.
- Quantity limits for patients less than 18 years of age to include:
 1. Short-acting CNS stimulants, not to exceed 3 dosage units daily with a maximum of 90 days per strength (for titration)
 2. Long-acting CNS stimulants, not to exceed 1 dosage unit daily with a maximum of 90 days.
- Quantity limits for patients 18 years of age and older to include:
 1. Short-acting CNS stimulants, not to exceed 3 dosage units daily with a maximum of 30 days

2. Long-acting CNS stimulants, not to exceed 1 dosage unit daily with a maximum of 30 days
 3. Diagnosis requirement for patients age 18 and older requesting greater than a 30-day supply
- Central Nervous System Stimulants should be brought to the New York State Pharmacy and Therapeutics Committee to be considered for inclusion in the Clinical Drug Review Program for patients 18 years and older.

Anabolic Steroids

The DUR Board took the following action(s) regarding Anabolic Steroids:

- Limitations for anabolic steroid products based on approved FDA labeled daily dosing and documented diagnosis not to exceed a 90-day supply (30-day supply for oxandrolone):
 - Initial duration limit of 3 months (for all products except oxandrolone), requiring documented follow-up monitoring for response and/or adverse effects before continuing treatment
 - Duration limit of 6 months for delayed puberty
 - Duration limit of 1 month for all uses of oxandrolone products
- Anabolic steroids should be brought to the New York State Pharmacy and Therapeutics Committee to be considered for inclusion in the Clinical Drug Review Program

The meeting adjourned at 3:30 pm