Drug Utilization Review (DUR) Board Meeting Summary December 2, 2011

Agenda and Introduction

The Drug Utilization Review Board met on Friday, December 2, 2011 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:

1. Patel, Bharat, Pharm.D., Medical Science Liaison, GlaxoSmithKline, Malvern, PA

2. Price, Arlene, Pharm.D., Sr. Liaison, Health Economics & Outcomes Research, Johnson & Johnson, Randolph, NJ

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

Omega-3-acid ethyl-esters (Lovaza):
The DUR Board was asked to consider information regarding the use of omega-3-acid ethyl-esters for the treatment of severe hypertriglyceridemia. A general overview of omega-3-acid ethyl-esters was presented including dosages, side effects, and indications, as well as information regarding clinical trial results and the reported adverse effects.

A Board member asked for clarification on bleeding potential and any impact on platelet function associated with omega-3-acid ethyl-esters, as well as the concomitant use with aspirin.

Tapentadol (Nucynta, Nucynta ER):
The DUR Board was asked to consider information regarding the use of tapentadol for the treatment of moderate to severe pain. A general overview of tapentadol was presented including dosages, side effects, and indications. The Board was also presented with studies comparing tapentadol to placebo and other opioid analgesics.

A Board member asked for information regarding the relationship between use of tapentadol and the risk of developing serotonin syndrome and/or seizures. A Board member also asked for clarification on the criteria used to select doses of other opioid analgesics and tapentadol when compared in the presented studies.

D. Presentations and Discussions:

The following speakers presented to the DUR Board:

1. Wrobel, Mark, Pharm.D., Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
2. Hong, Irene, Pharm.D., Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
3. Coe, Holly, Pharm.D., Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
4. 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
5. Lehmann, David, MD, Pharm.D., Professor of Medicine and Pharmacology, State University of New York Upstate Medical University
6. McNamara, Daniel, R.Ph., Medicaid Pharmacy Program, Office of Health Insurance Programs, New York State Department of Health
7. Toohey, Monica, R.Ph., Medicaid Pharmacy Program, Office of Health Insurance Programs, New York State Department of Health
8. Leonard, Kimberly, R.Ph., Medicaid Pharmacy Program, Office of Health Insurance Programs, New York State Department of Health
9. Counts, Katie, Pharm. D., Clinical Pharmacist/Account Manager, Health Information Designs, Inc.
10. Helgerson, Jason, Medicaid Director, Deputy Commissioner, Office of Health Insurance Programs, NYS Department of Health

Carisoprodol Containing Products
Dr. Wrobel and Ms. Toohey presented the carisoprodol utilization review. The DUR Board was provided with a general overview of the drug products available, including the indications, accepted uses and clinical considerations. The DUR Board was also provided with NYS Medicaid claims utilization information including utilization of specific carisoprodol products, number of claims, and duration of therapy. Dr. Wrobel reported the association with additional factors including potential over-utilization, misuse, and withdrawal which may be related to carisoprodol being metabolized to meprobamate which carries a C-IV designation. Prior authorization requirements from comparator state Medicaid programs were also reviewed.

Tapentadol
Dr. Hong and Ms.Toohey presented the tapentadol utilization review. The DUR Board was provided with a general overview of the immediate release (IR) and extended release (ER) products and their indications, dosing, and clinical concerns. The Board was also provided with NYS Medicaid claim utilization information, including quantity per claim, frequency of refills, cost considerations, evidence of utilization of IR formulation prior to utilization of ER formulation, and acute and chronic use. Prior authorization requirements from comparator state Medicaid programs were also reviewed.

Paliperidone
Dr. Coe and Mr. McNamara presented the paliperidone utilization review. The DUR Board was provided with a general overview of paliperidone including the indications, accepted uses, black box warnings, and clinical considerations. The Board was also provided with NYS Medicaid claim utilization information including evidence of indicated use, quantity per claim and the utilization of more cost effective comparable products, such as, risperidone prior to initiating paliperidone therapy. Prior authorization requirements from comparator state Medicaid programs were also reviewed.

Omega-3-acid ethyl-esters
Dr. Catanzaro and Mr. McNamara presented the omega-3-acid ethyl-esters utilization review. The DUR Board was provided with a general overview of the drug including the single FDA approved indication, and clinical considerations. The Board was also provided with NYS Medicaid claims utilization information including quantity dispensed, frequency of dispensing, duration of therapy, adherence, and previous utilization of a more cost effective therapy. Prior authorization requirements from comparator state Medicaid programs were also reviewed.

Meperidine
Ms. Toohey and Mr. McNamara presented the meperidine utilization review. The DUR Board was provided with a general overview of the drug including the indications, accepted uses and clinical considerations. The Board was also provided with NYS Medicaid claims utilization information including claim and beneficiary counts.

Opioid agonist/antagonist (butorphanol, pentazocine)
Ms. Toohey and Mr. McNamara presented the opioid agonist/antagonist (butorphanol, pentazocine) utilization review. The DUR Board was provided with a general overview of these drugs including the indications, accepted uses and clinical considerations. The Board was also provided with NYS Medicaid claims utilization information including claim and beneficiary counts.

Medicaid Redesign Team (MRT) Update
Mr. Helgerson presented an update on the Medicaid Redesign Team (MRT). The MRT overview covered the major reforms occurring during Phase I. The Board was also presented with next steps identified by the MRT work groups, including more complex issues in Phase II that could not be addressed within the short time frame of phase I. Mr. Helgerson concluded that ultimately Phase I and Phase II will be pulled together during a multiyear process and will bring together the whole depth of the recommendations that have been made by the team.

Prescriber Education Program (PEP)
Dr. Lehmann presented the Prescriber Education Program (PEP) update. Dr. Lehmann provided information pertaining to various ways the PEP can impact therapy across the State. The Board was also presented with a high level overview of programs that have been implemented as well as programs that are available as resources aligning the PEP and Medicaid Initiatives.

Pharmacy Claims Processing System Enhancements
Dr. Counts and Ms. Leonard presented the Pharmacy Claims Processing System Enhancements update. Dr. Counts provided the Board with information pertaining to system enhancements that will allow the implementation of previous actions taken by the Board.

E. DUR Board Discussion:

The DUR Board discussed the utilization of carisoprodol containing products and safety concerns in regards to adverse events and drug interactions. The Board also discussed the need to establish step edits and quantity limits. A Board member inquired about discontinuing coverage of carisoprodol containing products from the NYS Medicaid list of reimbursable drugs.

The DUR Board discussed the utilization of tapentadol in relation to other opioids and addiction potential as well as transitioning patients from short acting formulations to extended-release products when treating chronic pain. They discussed step therapy and the period associated with previous utilization of tramadol or another opioid-type pain reliever.

The DUR Board discussed the utilization of paliperidone in relation to initial use of more cost effective risperidone therapy and quantity limits for the treatment of FDA approved indications. The Board also discussed those patients that have obtained a prior approval and have established therapy going forward.

The DUR Board discussed omega-3-acid ethyl-esters in relation to the utilization and dosing for the treatment of the single FDA approved indication of severe hypertriglyceridemia. The Board also discussed the concerns with the omega-3-acid ethyl-esters raising high and low density lipids in patients. A Board member urged sending an education letter concerning treating the cause of high triglyceride levels rather than targeting lower triglyceride levels.

The DUR Board discussed the appropriate utilization of meperidine, butorphanol, and pentazocine containing products. They discussed the need for greater education on the safety profiles of these products and the need to monitor the population receiving these agents.

F. DUR Board Action:

Carisoprodol Containing Products

The DUR Board took the following action(s) regarding carisoprodol containing products:

- Trial with one (1) preferred analgesic and two (2) preferred skeletal muscle relaxants prior to use of carisoprodol containing products
- Maximum yearly quantity limit – 84 cumulative units per year
- Bring to Pharmacy and Therapeutics Committee for consideration to be placed in the Clinical Drug Review Program

Carisoprodol

- Maximum of 4 units per a day
- Maximum 21 day supply

Carisoprodol Combinations

- Maximum of 8 units per a day
- Maximum 21 day supply

Tapentadol
The DUR Board took the following action(s) regarding tapentadol:

- Trial with tramadol AND one (1) preferred opioid prior to tapentadol Immediate-Release (IR)
- Trial with a long acting preferred opioid and tapentadol IR before tapentadol ER
- Further analysis of data (utilization and clinical) regarding maximum daily dose of tapentadol to be conducted by SUNY and presented at the next DUR Board meeting

Tapentadol IR

- Maximum 6 units per day
- Maximum 180 units per 30 days

Tapentadol ER

- Maximum 2 units per day

Paliperidone
The DUR Board took the following action(s) regarding paliperidone:

- Trial with risperidone prior to initiation of paliperidone therapy
- Maximum 1 unit per day for 1.5mg, 3mg, and 9mg tablets
- Maximum 2 units per day for the 6mg tablet

Omega-3-acid ethyl-esters
The DUR Board took the following action(s) regarding omega-3-acid ethyl-esters:

- Trial with fibric acid derivative OR niacin prior to initiation of treatment with omega-3-acid ethyl-esters
- Requirement of 4 units per a day
- Provider letter

Meperidine
The DUR Board took the following action(s) regarding meperidine:

- Refer to Drug Information Resource Center (DIRC) for targeted prescriber intervention to address:
  - Toxicity (seizure risk)
  - Relative prescribing as compared to peers

- DoH to report to DURB outcome of educational effort deployed

Opioid agonist/antagonist (butorphanol, pentazocine)
The DUR Board took the following action(s) regarding opioid agonist/antagonist (butorphanol, pentazocine):

- Refer to Drug Information Resource Center (DIRC) for targeted prescriber intervention to address:
  - Toxicity
  - Relative prescribing as compared to peers
  - Specific to butorphanol: additional concerns due to route of administration

- DoH to report to DURB outcome of educational effort deployed

The meeting adjourned at 3:30 p.m.