

Drug Utilization Review (DUR) Board Meeting Summary December 7, 2012

Agenda and Introduction

The Drug Utilization Review Board met on Friday, December 7, 2012 from 9:00 A.M to 4:00 P.M., in Meeting Room 6, Concourse, Empire State Plaza, Albany, New York.

A. Background Materials

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

B. Public Comment Period

No speakers addressed the DUR Board during the public comment period.

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

No speakers addressed the DUR Board during the public comment period.

D. Presentations, Discussions, and Program Updates:

The following speakers presented to the DUR Board:

- Catanzaro, Linda, PharmD, Clinical Assistant Professor, Director, Pharmacotherapy Information Center Chair, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
- Coe, Holly, PharmD, Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
- Cogan, Lindsay, MS, New York State Department of Health, Office of Quality and Patient Safety
- Correia, Robert, PharmD, New York State Department of Health, Office of Health Insurance Programs
- Deloresco, Fred, PharmD, Clinical Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
- Finnerty, Molly, MD, Director, Bureau of Evidence Based Services & Implementation Science, NYS Psychiatric Institute, Office of Mental Health
- Hong, Irene, PharmD, Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
- Huggins, Charnicia, PharmD, Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
- Khadem, Tina, PharmD, Outcomes Research Fellow, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo

- Lehmann, David, MD, PharmD, Professor of Medicine and Pharmacology, State University of New York Upstate Medical University
- Naioti, John F., Jr., RPh, New York State Department of Health, Office of Health Insurance Programs
- Toohey, Monica M., RPh, New York State Department of Health, Office of Health Insurance Programs

System Enhancements

An update on the preferred drug program website was provided by Ms. Toohey. It was explained that there is now a single location that provides information and links to the various pharmacy management programs, including DUR parameters. In addition, the PAxpress program and its systematic interface were presented. Use of the web information was discussed.

DUR Informational Letters

An update on the DUR informational letters mailed to providers was presented by Mr. Naioti. DUR informational letters are a part of the Board's compliance with legislation requiring an educational program using data provided through DUR to provide for active and ongoing educational outreach programs to improve prescribing and dispensing practices.

Short Acting Opioids – Duration of Therapy

Dr. Hong presented information on drug utilization in the class of short-acting opioids. Presented information included FDA approved products, FDA approved indications, clinical considerations, and safety. In addition, comparisons by State for quantity limits and prior authorization were presented as well as managed care coverage of the drug. Further utilization, including duration of therapy, for the short acting opioids and its implication as a class were discussed.

Metozolv ODT (metoclopramide)

Dr. Hong presented clinical information with regard to the treatment of the FDA approved indications and compendia supported uses of metoclopramide. The common dosages, administration, and place in therapy were also presented. Safety of the drug, comparator State coverage, managed care coverage, and utilization were also discussed. The implications of the dosage form as well as risk of tardive dyskinesia were also presented.

Xifaxan (rifaximin)

Dr. Khadem presented clinical information with regard to treatment of hepatic encephalopathy and traveler's diarrhea with rifaximin. Information included FDA approved indications, compendia supported uses, unapproved indications, and place in therapy. The Medicaid utilization data was also reviewed, with consideration given to current Medicaid drug status, managed care coverage and cost effectiveness.

Anti-Retroviral (ARV) Medications – Drug Interactions

Dr. Catanzaro presented the clinical information and Medicaid data for antiretroviral drug interactions. This presentation was based on information from the US Department of Health and Human Services (DHHS) Panel. In addition, information from NY AIDS Drug Assistance

Program (ADAP) was incorporated. Dr. Catanzaro provided past DURB actions, the FDA approved ARVs, clinical considerations, safety, and utilization on ARV interactions. Both the interactions of ARVs with non-ARV drugs and ARVs with other ARVs were analyzed.

Acthar H.P. Gel (Repository corticotropin injection)

Dr. Coe presented clinical information with regard to treatment of infantile spasms and multiple sclerosis with the use of Acthar Gel. Additional information included FDA approved indications, compendia supported uses, dosage, administration, and place in therapy. The Medicaid utilization data was also examined with consideration given to current Medicaid drug status, comparator State coverage, managed care organization coverage, and cost effectiveness.

Drug Utilization Review Interventions

Dr. Deloresco presented a step therapy update for the following agents: Singulair, Lovaza, Moxatag, Doryx, Invega, and Restasis. The utilization of each of the agents pre and post intervention, was analyzed and discussed with the Board. It was concluded that the utilization and expenditures decreased for each group of agents except Restasis and artificial tears. Decreases in utilization were similar to decreases in the Fee for Service population.

Quality Measurement in Managed Care

Ms. Cogan presented program updates relating to measuring the quality for the health care delivery systems of managed care organizations. An overview of the Health Effectiveness Data & Information Set (HEDIS) measures and NYS Quality Assurance Reporting Requirements (QARR) were presented. Other topics that were presented included examples of quality measures, utilization reports, pharmacy benefit changes, challenges with the program, and upcoming projects.

Psychiatric Services and Clinical Knowledge Enhancement Systems (PSYCKES)

Dr. Finnerty presented the Psychiatric Services and Clinical Knowledge Enhancement Systems update. Dr. Finnerty presented information about the interactive web-based application, including instruction and examples on how to use the program. In addition, pilot sites and program engagement analyses were presented. Information about the usability, new consumer content and implementation were also provided.

Prescriber Education Program (PEP)

Drs. Lehmann, Catanzaro and Huggins provided information about the process for optimal, safe, efficacious, and fiscally responsible medication use. Enhanced prescriber education, community pharmacy initiatives, and web-based decision support processes were described within the program. It was found that most providers were interested in the continuing medical education (CME). Providers have recommended it to their colleagues. A majority of providers who replied stated that the PEP increased their knowledge or helped outcomes. The idea of controlled substance agreements between provider and patient were discussed. Additional discussion suggested the development of pain management guidelines for providers.

E. DUR Board Discussion:

Treatment options available for pain management were discussed. Some examples included the use of transcutaneous electrical nerve stimulation (TENS) and opioid pumps. A comprehensive education process on medication usage that included the tricyclic antidepressants (TCAs) and antiepileptic drugs for pain was discussed. There was dialogue concerning the development of guidelines for TCAs, antiepileptics, buprenorphine, and tramadol in the treatment of pain. There was discussion concerning the overuse of opioid medications and diversion. Development of programs for providers relating to pain management was discussed as well as the need to monitor the use of opioids in patients. Patient and prescriber agreements were advocated in the discussion. Drug tests and how to they determine levels of drugs in the body were discussed. Overall agreement on prescriber education, monitoring prescribing activity and the I-STOP program was also discussed.

The utilization of metoclopramide was discussed. Patients with diabetic gastroparesis and their inability to tolerate oral dosage forms due to vomiting were explained. Discussion for the disintegrating tablet for that specific population proceeded. There was also discussion on the use of metoclopramide in Parkinson's patients.

The DUR Board discussed the clinical use of fluoroquinolones as first line therapy in traveler's diarrhea. Conversely, rifaximin should be given no restriction in treating hepatic encephalopathy. There was discussion on the use in hepatic encephalopathy and the sourcing of the tablets and the quantity limits. The ability to turn off the quantity limit edit during periods of drug shortages was also discussed.

The DUR Board discussed the dose adjustments required for certain antiretrovirals when there is potential for drug to drug interactions. In addition, data representing the switching of antiretroviral therapies was discussed. There was also discussion on the process of the clinical editing for the interactions through the pharmacy claims system including Prospective DUR (ProDUR). There was further discussion on updating providers about proposed implementation of edits.

The DUR Board discussed the most recent data on the use of Acthar through a preliminary study that was presented at the American Epileptic Society convention. The use of Acthar in multiple sclerosis (MS) exacerbations and patients with inadequate intravenous (IV) access was considered. There was also discussion about steroid use prior to treatment with Acthar. Dr. Correia provided comment relating to previous and current studies pertaining to Acthar therapy versus steroid therapy.

F. DUR Board Action:

Anti-Retroviral (ARV) Medications – Drug Interactions

The DUR Board took the following action(s) regarding ARV Medications - Drug Interactions:

- Prospective DUR edit for contraindicated antiretroviral/non-antiretroviral combinations.*
- Prospective DUR edit for contraindicated antiretroviral/antiretroviral combinations.*
- DUR Educational Program: Educational outreach to providers or prescriber specific intervention letters highlighting clinically significant drug interactions with ARV therapy and recommended management strategies

*Clinical Call Center must be contacted to override edit

Short Acting Opioids – Duration of Therapy

The DUR Board took the following action(s) regarding duration of therapy for short acting opioids:

- Duration Limit*: 90 days for patients without a diagnosis of cancer or sickle-cell disease

*Excluding tramadol containing products

Metozolv ODT (metoclopramide)

The DUR Board took the following action(s) regarding use of Metozolv ODT:

- Step therapy**: trial with conventional metoclopramide before metoclopramide ODT
- Quantity limit: 4 units per day, 120 units per 30 days.
- Duration limit: 90 days.

** Electronic bypass for previous therapy with conventional metoclopramide or diagnosis of diabetes

Xifaxan (rifaximin)

The DUR Board took the following action(s) regarding Xifaxan (rifaximin):

- Confirm diagnosis of hepatic encephalopathy or traveler's diarrhea.*
- Step therapy: Trial of a preferred fluoroquinolone before rifaximin for diagnosis of traveler's diarrhea.
- Quantity limit: 60 tablets per 30 days of the 550 mg tablets for the diagnosis of hepatic encephalopathy. **
- Quantity limit: 9 tablets per 30 days of the 200 mg tablets for the diagnosis of traveler's diarrhea. ***

*Electronic Bypass for covered diagnosis identified in the claims system.

** Recommended dose of rifaximin for hepatic encephalopathy is 550mg given 2 times daily.

*** Recommended dose of rifaximin for traveler's diarrhea is 200mg given 3 times daily for 3 days.

Acthar H.P. Gel (repository corticotropin injection)

The DUR Board took the following action(s) regarding Acthar H.P. Gel (repository corticotropin injection):

- Confirm diagnosis for Medicaid covered uses.*
- Step Therapy: Trial of first-line therapy for all FDA-approved indications other than infantile spasms. **
- Duration limits: based on diagnosis.
 1. Infantile spasms: 4 weeks (indicated for <2 years of age)
 2. Multiple Sclerosis (MS): 5 weeks
 3. Rheumatic disorders: 5 weeks
 4. Dermatologic conditions: 5 weeks

5. Allergic states (serum sickness): 5 weeks

- Quantity limits:

1. Infantile spasms: maximum of 30 mL (six 5 mL vials)
2. MS: maximum of 35 mL (seven 5 mL vials)

* Electronic bypass for covered diagnosis identified in the claims system. FFS pharmacy benefit does not cover for diagnostic purposes.

** Acthar is first line therapy for infantile spasms in children less than 2 years of age- step therapy not required.

The meeting adjourned at 3:30 P.M.