

Drug Utilization Review (DUR) Board Meeting Summary March 8, 2012

Agenda and Introduction

The Drug Utilization Review Board met on Thursday, March 8, 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 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. Dudzinski-Johnson, Linda, PharmD, Global Health Outcomes Liaison, Eli Lilly and Company, Indianapolis, IN
2. Sill, Bruce, PharmD, Executive Manager, Clinical Science & Outcomes, Takeda Pharmaceuticals America, Deerfield, IL
3. Hanks, Rebecca, Consumer Advocate, Glenmont, NY
4. Pryor, Cheryl, PharmD, Medical Liaison, Managed Markets, Novo Nordisk, Princeton, NJ

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

Selective Serotonin Reuptake Inhibitors/Serotonin-Norepinephrine Reuptake Inhibitors

Testimony provided a general overview of Cymbalta including indications, dosages and side effects. It was noted that it has a new indication for chronic musculoskeletal pain such as chronic low back pain and osteoarthritis.

Board members questioned design, dosing and results of studies discussed.

Lubiprostone

Testimony provided a general overview of Amitiza including indications, dosages and side effects. It was noted that it is the only medication approved by the FDA for irritable bowel syndrome with constipation in women.

A Board member commented on the drug's mechanism of action and questioned whether it was a better alternative to more cost-effective drugs already available.

Angiotensin Converting Enzyme Inhibitors/Angiotensin Receptor Blockers/Direct Renin Inhibitors

Testimony provided a general overview of azilsartan containing products, including indications, dosages and side effects.

A Board member inquired about head-to-head studies between the classes being reviewed.

Human Growth Hormone (HGH)

Testimony included personal experience with the use of growth hormone in a child with a diagnosis of Small for Gestational Age secondary to Russell Silver Syndrome. It was urged that the Board not drop Medicaid coverage for human growth hormone.

Testimony also provided a general overview of HGH, including indications and dosages.

D. Presentations and Discussions:

The following speakers presented to the DUR Board:

1. 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
2. Chandler, Diana, PharmD, Academic Educator, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
3. Coe, Holly, PharmD, Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
4. Finnerty, Molly, MD, Director of the Bureau of Evidence Based Services & Implementation Science, NYS Psychiatric Institute, Office of Mental Health
5. Lehmann, David, MD, PharmD, Professor of Medicine and Pharmacology, State University of New York Upstate Medical University
6. Manley, Harold, PharmD, Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
7. McNamara, Daniel, RPh, Medicaid Pharmacy Program, Office of Health Insurance Programs, New York State Department of Health

8. Toohey, Monica, RPh, Medicaid Pharmacy Program, Office of Health Insurance Programs, New York State Department of Health

Morphine and Congeners

Ms. Toohey addressed old business regarding limits that were placed on some extended release morphine products, specifically MS Contin® 100 mg and 200 mg tablets, as discussed at the October 20, 2011 DUR Board meeting. The DUR Board was provided with information that would allow for the maximum dose on those strengths to be more in line with other available extended release morphine products.

Tapentadol

Ms. Toohey addressed old business from the previous DUR Board meeting concerning the dosing limits on tapentadol immediate release (IR) and extended release (ER) products when used in combination. The DUR Board was provided with studies related to the dosing of these products when used concomitantly as well as current NYS Medicaid claims utilization information including number of beneficiaries using tapentadol IR and ER concurrently. Ms. Toohey also provided clarification to the previous DURB recommendation which required a trial with tapentadol IR and a long acting preferred opioid before tapentadol ER.

Selective Serotonin Reuptake Inhibitors/Serotonin-Norepinephrine Reuptake Inhibitors

Dr. Coe presented the selective serotonin reuptake inhibitors (SSRI)/serotonin-norepinephrine reuptake inhibitors (SNRI) utilization review. The DUR Board was provided with a general overview of the drug classes including the indications, accepted uses and clinical considerations. The Board was also provided with NYS Medicaid claims utilization information including average cost of therapy, number of beneficiaries that had a trial with an SSRI before starting an SNRI, and diagnosis information.

Human Growth Hormone

Dr. Coe presented the HGH utilization review. The DUR Board was provided with a general overview of the drug class including the indications, accepted uses, clinical considerations and previous DUR Board and Pharmacy & Therapeutics Committee recommendations regarding HGH. The Board was also provided with NYS Medicaid claims utilization information including diagnosis and total claim cost, and the association with additional factors including potential over-utilization and misuse. The Board was informed of the Medicaid Redesign Team's final recommendation on HGH, which concluded that HGH not be covered under the NYS Medicaid program for the diagnosis of Idiopathic Short Stature.

Lubiprostone

Dr. Catanzaro presented the lubiprostone 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 the NYS Medicaid claims utilization information including strength and quantity dispensed, utilization by age for lubiprostone, other laxatives used in the treatment for same medical conditions and the association with additional factors including potential over-utilization and misuse.

Long Acting Beta Agonists

Dr. Manley presented the long acting beta agonists utilization review. The DUR Board was provided with a general overview of the drug class including the indications and clinical considerations, clinical guidelines for the use in asthma treatment, and current NYS prospective and retrospective utilization review system edits. The Board was also provided with the NYS Medicaid information regarding drug class utilization in beneficiaries with asthma and those without a medical claim for asthma or chronic obstructive pulmonary disease and the association with additional factors including use with inhaled corticosteroids.

Angiotensin Converting Enzyme Inhibitors/Angiotensin Receptor Blockers/Direct Renin Inhibitors (ACEI/ARB/DRI)

Mr. McNamara presented the ACEI/ARB/DRI utilization review. The DUR Board was provided with a general overview of the drug classes including the indications, accepted uses, clinical considerations, and relative cost. The Board was also provided with the NYS Medicaid claims information including utilization, previous therapy, and the association with additional factors including number of beneficiaries that had a trial with an ACEI before starting an ARB and trial with an ACEI or ARB before starting a DRI.

Pharmacy Claim System Enhancements Update

Ms. Toohey presented to the DUR Board updates on the status of the pharmacy claim system enhancements. She discussed automatic prior authorization when a claim satisfies the clinical criteria rules, current messaging for clinical rule failure, and web-based prior authorization requests under development. She also informed the Board that the majority of past recommendations made have been implemented. Ms. Toohey explained NYS Medicaid will continue to implement DUR Board and Pharmacy & Therapeutics Committee recommendations going forward using Health Information Design's automated prior authorization system, RxPert®.

Prescriber Education Program (PEP)

Dr. Lehmann presented the Prescriber Education Program (PEP) update. Dr. Lehmann and Dr. Chandler demonstrated a typical visit interaction between an academic educator and a prescriber.

Psychiatric Services and Clinical Knowledge Enhancement Systems (PSYCKES)

Dr. Finnerty presented the Psychiatric Services and Clinical Knowledge Enhancement Systems update. Dr. Finnerty presented to the Board information demonstrating the current quality indicators used by the PSYCKES program regarding free-standing mental health clinics and the ability of hospital mental health clinics to meet these quality indicators.

E. DUR Board Discussion:

The DUR Board discussed the limits placed on MS Contin® in relation to other extended release morphine products. The Board also discussed frequency limits that should be placed on MS Contin® to correspond with the Food and Drug Administration (FDA) labeling, maximum daily dosages and flexibility of dosing.

The DUR Board discussed the utilization of tapentadol IR and ER in relation to concomitant maximum daily dosing based on FDA labeling and use supported by current clinical studies. They also discussed the appropriateness of requiring a trial of the tapentadol IR prior to ER for patients naïve to long acting opioids.

The DUR Board discussed the utilization of SSRIs and SNRIs in relation to diagnosis, cost, and place in therapy. The Board was provided with the additional indications carried by SNRIs: chronic musculoskeletal pain, diabetic peripheral neuropathy, and fibromyalgia. The Board discussed using step therapy requiring a trial of a preferred SSRI prior to a preferred SNRI, except in those cases where those diagnoses mentioned above where SSRIs are not indicated.

The DUR Board discussed current requirements for reimbursement of HGH, and adding to the current requirements reporting of a covered diagnosis, regardless of patient age. The Board further discussed that manual reporting would be bypassed when system editing detects a history of a covered diagnosis within the electronic claims system. The Board also discussed the Medicaid Redesign Team's recommendation that idiopathic short stature not be a covered diagnosis.

The DUR Board discussed the utilization of lubiprostone in relation to approved indications, quantity and duration limits based on FDA labeling. The Board discussed lubiprostone place in therapy in relation to other drugs used for chronic idiopathic constipation and irritable bowel syndrome with constipation. The Board also discussed implementing step therapy as well as frequency/quantity/duration limits for the use of lubiprostone.

The DUR Board discussed the utilization of long acting beta agonists in relation to concomitant inhaled corticosteroid use and place in therapy. The Board also discussed sending an educational letter to targeted prescribers detailing appropriate use of long acting beta agonists and creation of a prospective drug utilization review edit to alert a pharmacist dispensing a long acting beta agonist that a beneficiary with asthma is not concurrently taking an inhaled corticosteroid.

The DUR Board discussed the utilization of angiotensin converting enzyme inhibitors, angiotensin receptor blockers, and direct renin inhibitors in relation to cost, and place in therapy for each class. The DUR Board also discussed implementing a two part class step therapy based on current clinical evidence, requiring a trial of a preferred angiotensin converting enzyme inhibitor prior to a preferred angiotensin receptor blocker and a trial of either an angiotensin converting enzyme inhibitor or angiotensin receptor blocker before initiating treatment with a preferred direct renin inhibitor.

F. DUR Board Action:

Tapentadol

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

- Quantity limit: maximum daily dose of tapentadol IR and tapentadol ER formulations if used in combination should not exceed 500mg/day.
- Step Therapy: Require a trial with tapentadol IR before tapentadol ER in patients who are naïve to a long-acting opioid.

Morphine and Congeners

The DUR Board took the following actions(s) regarding morphine and congeners for non-cancer and non-sickle cell disease:

- Quantity limit for extended-release (ER) products:
 - Morphine ER (MS Contin® 100mg only): maximum 4 units per day up to 3 times a day frequency, 120 units per 30 days
 - Morphine ER (MS Contin® 200mg only): maximum 2 units per day, 60 units per 30 days.

Selective Serotonin Reuptake Inhibitors/Serotonin-Norepinephrine Reuptake Inhibitors

The DUR Board took the following action(s) regarding selective serotonin reuptake inhibitors/serotonin-norepinephrine reuptake inhibitors:

- Step therapy: Require trial with an SSRI prior to an SNR
(Exception for specific indications: Chronic Musculoskeletal Pain, Diabetic Peripheral Neuropathy, and Fibromyalgia)

Human Growth Hormone

The DUR Board took the following action(s) regarding human growth hormone:

- Prior authorization required for lack of diagnosis of covered medical conditions for all human growth hormone products regardless of patient age.
- No changes recommended to current prior authorization requirement for Growth Hormone under Clinical Drug Review Program for beneficiaries 21 years of age and older.

Lubiprostone

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

- Step therapy: Require trials of both a bulking-agent and an osmotic laxative prior to lubiprostone (recommended a 89 day look back).
- Duration limit: 30 days with 2 refills per prescription.

Long Acting Beta Agonists

The DUR Board took the following action(s) regarding long acting beta agonists:

- Provider letter: Educational letter to targeted prescribers regarding National Heart Lung and Blood Institute treatment guidelines for the management of asthma patients.
- Prospective DUR: Create a prospective DUR edit warning a pharmacist attempting to dispense a LABA prescription that the beneficiary does not have a recent history or concurrent ICS claim.

Angiotensin Converting Enzyme Inhibitors/Angiotensin Receptor Blockers/Direct Renin Inhibitors

The DUR Board took the following action(s) regarding Angiotensin Converting Enzyme Inhibitors (ACEI) /Angiotensin Receptor Blockers (ARB) /Direct Renin Inhibitors (DRI) :

- Step therapy: Trial of a product containing an ACEI prior to initiating a preferred ARB.
- Step therapy: Trial of a product containing either an ACEI or an ARB prior to initiating a preferred DRI

The meeting adjourned at 2:45p.m.