New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for March 6, 2014

The Medicaid DUR Board met on Thursday, March 6, 2014 from 10:00 AM to 4:00 PM in Meeting Room 3, Concourse, Empire State Plaza, Albany, New York

An archived audio webcast of the meeting proceedings is available on the Department of Health website for 60 days from the meeting date: http://www.health.ny.gov/events/webcasts/

A. Welcome and Introductions (Audio Webcast Time 0:00:12- 0:02:20)

Department of Health Staff
Anthony Merola, RPh, MBA
Robert Correia, PharmD
John Naioti, RPh

DUR Board Members
Michelle Rainka, PharmD
William Scheer, RPh
James Saperstone, MD
Marla Eglowstein, MD
Jadwiga Najib, PharmD
Renante Ignacio, MD
Nancy Balkon, PhD, NP
Donna Chiefari, PharmD
John Wikiera

SUNY – University at Buffalo Staff
Barbara Rogler, PharmD, MS
Linda Catanzaro, PharmD
Holly Coe, PharmD
Irene Hong, PharmD

B. Public Comment Period

The following speakers provided public comment to the DUR Board:

1. Matthew Goodwin, Medical Science Liaison, Salix Pharmaceuticals, Inc. - Fulyzaq
2. Carol Spelman, MS, Medical Science Liaison, Aegerion Pharmaceuticals, Inc. - Juxtapid
3. Drew Revel, PhD, Sr. Medical Science Liaison, Genzyme Corporation - Kynamro
4. Jeffrey Olsen, PharmD, Associate Direct Med Science, Gilead - Sovaldi
5. Jennifer Stoffel, PharmD, Principal Liaison HECOR, Janssen Pharmaceuticals, Inc. – Olysio
C. Presentations and Recommendations  

1. Review of Second Generation Antipsychotics and CNS Stimulants concurrent utilization  

Dr. Barbara Rogler presented a review of concurrent utilization of second generation antipsychotics (SGA) and central nervous system (CNS) stimulants in children and adolescents utilization for the Medicaid managed care (MC) and fee-for-service (FFS) pharmacy programs. Therapies for attention deficit hyperactivity disorder (ADHD) with comorbid aggression, oppositional-defiant disorder (ODD), or conduct disorder (CD), known collectively as disruptive behavior were considered. Rate of occurrence of adverse drug events, potential metabolic effects, and the prescribing patterns of providers were discussed.

The DUR Board recommended the following:

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<th>1. For beneficiaries below the age of 18 years of age on concurrent CNS stimulant and SGA therapy:</th>
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<td>Confirm diagnoses that support the concurrent utilization of the CNS stimulant and SGA medication.</td>
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<td>Absence of covered diagnosis in patient’s claim history will require prescriber involvement.</td>
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<td>Passed Unanimously</td>
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<th>2. Establish a retrospective drug utilization review criterion enabling evaluation of concurrent use of CNS stimulants and SGA not prescribed by the same provider.</th>
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<td>Passed Unanimously</td>
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2. Review of dextromethorphan/quinidine (Nuedexta) utilization  

Dr. Holly Coe presented a review of dextromethorphan/quinidine (Nuedexta) utilization. The review considered the American Academy of Neurology (AAN) 2009 ALS guidelines, specifically the area concerning this medication used in the treatment of pseudobulbar affect (PBA). Adverse events and contraindications were considered, and a comprehensive breakdown of utilization by diagnosis was presented.

The DUR Board recommended the following:
1. Confirm diagnosis for FDA-approved indication:
   Pseudobulbar affect, secondary to multiple sclerosis or amyotrophic lateral sclerosis in patients ≥ 18 years of age.
   Absence of covered diagnosis in patient’s claim history will require prescriber involvement.
   Passed Unanimously

2. Quantity limit:
   (Based on FDA approved prescribing information)
   Two (2) capsules per day (60 units per 30 days)
   Passed Unanimously

3. Duration Limit: 90 days of therapy
   (Promote evaluation of therapy after 90 day as PBA symptoms may improve spontaneously)
   Passed Unanimously


Dr. Irene Hong presented a review of crofelemer (Fulyzaq) utilization. The review specified that the medication is indicated solely for symptomatic relief of non-infectious diarrhea in adult patients with human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS) on antiretroviral therapy (ART). The review stated that there were no clinical trials comparing crofelemer with other antidiarrheal agents, and that additional clinical trials are needed to determine long-term safety and efficacy and comparative efficacy.

The DUR Board recommended the following:

1. Confirm diagnosis of HIV/AIDS or ART therapy in claims history.
   Absence of evidence of covered diagnosis or anti-retroviral therapy in patient’s claim history will require prescriber involvement.
   Passed Unanimously

2. Step Therapy: trial with alternative anti-diarrheal agent.
   Override will require prescriber involvement.
   Passed Unanimously
4. Review of new treatments for homozygous familial hypercholesterolemia: 
lomitapide (Juxtapid) and mipomersen (Kynamro) 

Dr. Irene Hong presented a review of new treatments for homozygous familial 
hypercholesterolemia (HoFH), namely lomitapide (Juxtapid) and mipomersen (Kynamro). 
The review specified that the products are used as adjuncts to dietary modification and other 
lipid-lowering medications for reduction of cholesterol levels. The review noted that these 
newly approved medications carry safety concerns, and that they are not first-line agents.

The DUR Board recommended the following:

1. Confirm diagnosis of homozygous familial hypercholesterolemia
   Absence of covered diagnosis in patient’s claim history will require prescriber 
   involvement.
   Passed Unanimously

2. Step Therapy: Trial with high intensity statin therapy.
   Override will require prescriber involvement.
   Passed Unanimously

5. Hepatitis C Virus Clinical Criteria 

Dr. Linda Catanzaro presented a report on Hepatitis C Virus clinical criteria that discussed 
the place in therapy for the new medications, simeprevir (Olysio) and sofosbuvir (Sovaldi). 
Their place in therapy and monitoring required for use of these medications were 
considered. The Medicaid FFS clinical criteria were reviewed for these medications, and the 
value of continual updating of clinical criteria was reinforced. The reported concluded with 
the need for judicious screening and monitoring to ensure safe and effective use in 
appropriate patients.

6. Drug Utilization Review Evaluation 

Dr. Barbara Rogler presented the Drug Utilization Review evaluation. The purpose of the 
report was a post implementation evaluation of step therapy edits implemented in April 
2012 within the Medicaid FFS pharmacy benefit. The evaluation included the following 
drug/drug classes:
1. Angiotensin Receptor Blockers (ARBs), ARBs/ Calcium Channel Blockers (CCBs), ARB/ Diuretics and Direct Renin Inhibitors (DRIs)
2. Amitiza (lubiprostone)
3. Metozolv ODT (metoclopramide orally disintegrating tablets)
4. Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)
5. Nucynta Immediate and Extended-Release (tapentadol)

The report suggests the implementation of the step therapy criteria.
- Increase in compliance to the step therapy edit recommendations
- Increase in auto bypass clinical authorizations
- Increase in appropriate use of first line agents

D. Final Comments and Adjournment (Audio Webcast Time 03:56:50 - 04:01:16)

John Naioti, RPh
Anthony Merola, RPh, MBA

The meeting adjourned at 3:30 P.M.

Posted 3/24/2014