

**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

Monica Toohey, RPh
Robert Sheehan, 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

(Audio Webcast Time 0:20:38 – 3:29:38)

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

(Audio Webcast Time 0:22:00 - 1:25:54)

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:

1. For beneficiaries below the age of 18 years of age on concurrent CNS stimulant and SGA therapy:

Confirm diagnoses that support the concurrent utilization of the CNS stimulant and SGA medication.

Absence of covered diagnosis in patient's claim history will require prescriber involvement.

Passed Unanimously

2. Establish a retrospective drug utilization review criterion enabling evaluation of concurrent use of CNS stimulants and SGA not prescribed by the same provider.

Passed Unanimously

2. Review of dextromethorphan/quinidine (Nuedexta) utilization

(Audio Webcast Time 1:26:05 - 1:55:33)

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:

<p>1. Confirm diagnosis for FDA-approved indication:</p> <p>Pseudobulbar affect, secondary to multiple sclerosis or amyotrophic lateral sclerosis in patients \geq 18 years of age.</p> <p>Absence of covered diagnosis in patient's claim history will require prescriber involvement.</p> <p style="text-align: right;">Passed Unanimously</p>
<p>2. Quantity limit:</p> <p>(Based on FDA approved prescribing information)</p> <p>Two (2) capsules per day (60 units per 30 days)</p> <p style="text-align: right;">Passed Unanimously</p>
<p>3. Duration Limit: 90 days of therapy</p> <p>(Promote evaluation of therapy after 90 day as PBA symptoms may improve spontaneously)</p> <p style="text-align: right;">Passed Unanimously</p>

3. Review of crofelemer (Fulyzaq) utilization (Audio Webcast Time 1:56:24 - 02:28:58)

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:

<p>1. Confirm diagnosis of HIV/AIDS or ART therapy in claims history.</p> <p>Absence of evidence of covered diagnosis or anti-retroviral therapy in patient's claim history will require prescriber involvement.</p> <p style="text-align: right;">Passed Unanimously</p>
<p>2. Step Therapy: trial with alternative anti-diarrheal agent.</p> <p>Override will require prescriber involvement.</p> <p style="text-align: right;">Passed Unanimously</p>

4. Review of new treatments for homozygous familial hypercholesterolemia: lomitapide (Juxtapid) and mipomersen (Kynamro)

(Audio Webcast Time 2:29:40 - 02:46:57)

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

(Audio Webcast Time 02:47:30 - 03:29:38)

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 report concluded with the need for judicious screening and monitoring to ensure safe and effective use in appropriate patients.

6. Drug Utilization Review Evaluation

(Audio Webcast Time 03:29:50 - 03:56:50)

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.

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