

**New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for November 20, 2014**

The Medicaid DUR Board met on Thursday, November 20, 2014 from 9:00 AM to 3:30 PM
Meeting Room 3, Concourse, Empire State Plaza, Albany, New York

An archived audio cast of the meeting proceedings is available on the Department of Health website:
<http://www.health.ny.gov/events/webcasts/>

A. Welcome and Introductions

(Audio Cast Time 00:00 - 2:43)

Department of Health

Janet Zachary-Elkind
Robert Correia, PharmD
Anthony Merola, RPh, MBA

John Naioti, RPh
Robert Sheehan, RPh
Monica Toohey, RPh

DUR Board

Lisa Anzisi, PharmD
Nancy Balkon, PhD, NP
Donna Chiefari, PharmD
Jeffrey Dubitsky, RPh

Jadwiga Najib, PharmD
John Noviasky, PharmD
Anita Radix, MD
William Scheer, RPh

SUNY – University at Buffalo

Holly Coe, PharmD
Irene Hong, PharmD

Barbara Rogler, PharmD, MS
Diana Nagrecha, PharmD

AIDS Institute

Charles Gonzalez, MD

Office of Mental Health

Gregory Miller, MD

B. Old Business

(Audio Cast Time 02:44 - 04:05)

In reference to the tetrabenazine (Xenazine) agenda item reviewed at the September 18, 2014 meeting: DUR staff evaluated the ProDUR criteria that is in place on the electronic Medicaid claim system. Xenazine has a hard stop when interacting with monoamine oxidase inhibitors (MAOIs), reserpine and levodopa. The interaction with CYP2D6 inhibitors is a dose reduction alert in the ProDUR system. The RetroDUR program will be monitoring the claim activity related to Xenazine RetroDUR criteria. All Xenazine interactions discussed by the DUR Board at the September meeting are covered by RetroDUR criteria, and are presently active through our DUR vendor, Health Information Designs, Inc.

C. Public Comment Period

(Audio Cast Time 04:06 - 55:02)

The following people provided public comment to the DUR Board:

	<u>Name</u>	<u>Affiliation</u>	<u>Agenda Topic</u>
1.	Roderick Teat, PharmD	Otsuka	SG Antipsychotics
2.	Patty Marchlowska, RN	Eli Lilly	CNS Stimulants/Non-stimulants
3.	Christine Dube, PharmD	AstraZeneca	RSV Prophylaxis
4.	Brian Tevlin	Merck	Oral Pollen/Allergen Extracts
5.	Christine Dube, PharmD	AstraZeneca	Metreleptin
6.	Jeffrey Olsen, PharmD	Gilead	HCV – Newer Therapies
7.	Lillian de Mauro	UHAP	HCV – Newer Therapies
8.	Jules Levin	NATAP	HCV – Newer Therapies
9.	Tracey Swan	Treatment Action Group	HCV – Newer Therapies
10.	Luis Santiago	Act UpNY	HCV – Newer Therapies
11.	Matt Curtis, MPH	VOCAL-NY	HCV – Newer Therapies
12.	Valerie Reyes	Housing Works	HCV – Newer Therapies
13.	Alan T. Lunceford	End AIDS Now	HCV – Newer Therapies
14.	Jeton Ademaj	n/a	HCV – Newer Therapies
15.	Annette Gaudino	n/a	HCV – Newer Therapies
16.	Violet Armstead	n/a	HCV – Newer Therapies

D. Drug Utilization Reviews

(Audio Cast Time 0:55:05 - 4:56:20)

1. Metreleptin (Myalept)

(Audio Cast Time 0:56:05 - 1:25:14)

Dr. Holly Coe presented a review of metreleptin (Myalept), a medication that is FDA-approved for the treatment of congenital or acquired generalized lipodystrophy. Currently, metreleptin is not listed in the New York State (NYS) Medicaid fee-for-service (FFS) formulary. Dr. Coe presented the place in therapy for the drug, with recommendations to the Department of Health in assessing its proper use. The product's FDA indication, as well as FDA labeling specifically state that it is not indicated for certain other uses inclusive of other lipodystrophies or general obesity. Dose and administration along with the involved pharmacology was reviewed. Dr. Coe noted the drug's potential for complications as well as the recognition of safety concerns: boxed warning of the potential risk for the development of anti-metreleptin antibodies with neutralizing activity which could lead to severe infections and hematological abnormalities. Board discussion also included the potential for off-label use of the medication in weight reduction and the need for assessment of proper utilization.

The DUR Board recommended the following (1:18:52 - 1:25:14):

Confirm diagnosis for the FDA-approved indications:

Leptin deficiency in patients with congenital generalized lipodystrophy (CGL) or acquired generalized lipodystrophy (AGL)

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

Passed Unanimously

Educational intervention highlighting:

- Safety issues regarding the metreleptin boxed warning and development of anti-metreleptin antibodies with neutralizing activity, which may cause severe infection or lack of efficacy.
- Risk for development of T-cell lymphoma

Passed Unanimously

2. Oral Pollen/Allergen Extracts (Grastek, Oralair, Ragwitek)

(Audio Cast Time 1:25:28 - 2:06:30)

Dr. Holly Coe presented a review of the clinical pharmacology, efficacy, and safety of sublingual (SL) allergen extract products, Grastek®, Oralair® and Ragwitek™. Currently, these products are not listed in the New York State (NYS) Medicaid fee-for-service (FFS) formulary. The place in therapy of these sublingual immunotherapy (SLIT) medications was addressed and compared to current treatment methodologies, specifically subcutaneous

immune therapy. Meta-analysis was also presented that concluded comparable effect between sublingual immunotherapy, nasal corticosteroids, and nasal azelastine/fluticasone. The Board discussed the World Health Organization (WHO) suggestion that second generation antihistamines and intranasal corticosteroids are recommended for initial treatment. Safety issues and contraindications with the SL allergen extract products were discussed, with the boxed warning of life threatening allergic reactions (anaphylaxis) being the most severe. The Board also discussed the specifics of pre-treatment testing, and the consideration of age parameters for coverage.

The DUR Board recommended the following (1:56:38 - 2:06:30):

<p>Confirm diagnosis for the FDA-approved indication:</p> <p>Pollen-induced allergic rhinitis confirmed by positive skin or in vitro testing for pollen-specific IgE antibodies.</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>Step Therapy:</p> <p>Trial with a preferred intranasal corticosteroid</p> <p>Override will require prescriber involvement.</p> <p style="text-align: right;">Passed Unanimously</p>
<p>Educational intervention highlighting:</p> <ul style="list-style-type: none"> • Administration of a skin test for grass or ragweed pollens or <i>in vitro</i> testing for grass and ragweed-pollen specific IgE antibodies prior to initiation of treatment. • Safety issues regarding life-threatening allergic reaction such as anaphylaxis and severe laryngopharyngeal restriction, and including observation of patients in the office for a minimum of 30 minutes following first administration of oral allergen products. • World Health Organization guidelines for treatment of allergic rhinitis. <p style="text-align: right;">Passed Unanimously</p>

3. Second Generation Antipsychotics (SGA) utilized in the treatment of Major Depressive Disorder (MDD) (Audio Cast Time 2:06:32 - 2:51:50)

Dr. Irene Hong presented a review of the utilization of second generation antipsychotics (SGA) as an adjunct treatment for major depressive disorder (MDD). The utilization review focused on FDA indications and compendia support, medication adherence, and metabolic complications after initiation of SGA therapy. The Board discussed the place in therapy, safety and interactions of these agents, as well as clinical criteria adopted by comparator states. The Board also discussed the need to allow for patient assessment and use of SGAs in diagnoses of severe and psychotic depression as well as other evidence to indicate these conditions. The Board discussed the proposed recommendation that would allow for therapy continuation based on the existence of psychiatric co-morbidities.

The DUR Board recommended the following (2:41:36 - 2:51:50):

Diagnosis requirement for all SGA prescriptions. Absence of covered diagnosis in patient's claim history for beneficiaries not currently on therapy will require prescriber involvement.	Passed Unanimously
Step Therapy for all SGA prescribed for treatment of MDD in the absence of other psychiatric comorbidities: Trial with at least 2 different antidepressants	Passed Unanimously
Educational intervention addressing: <ul style="list-style-type: none">• The use of SGAs not approved for treatment of MDD, in the absence of any other psychiatric comorbidities.• Use of SGAs as monotherapy for treatment of MDD.	Passed Unanimously

4. Hepatitis C Virus - Recently Approved Therapies (Audio Cast Time 2:53:26 - 3:36:05)

Dr. Barbara Rogler presented a review of recently approved therapies utilized in the management of chronic hepatitis C (CHC) infection, including the newest agent ledipasvir/sofosbuvir (Harvoni) recently introduced into the marketplace. The Board discussed the guidelines for therapy as referenced by the American Association for the Study of Liver Disease (AASLD), the Infectious Diseases These guidelines serve as the basis of the hepatitis C protocol currently in use by the New York State Medicaid program. The chemical characteristics, indication, warnings and precautions, adverse reactions, drug interactions, as well as cost comparisons with other therapies was provided for ledipasvir/sofosbuvir

(Harvoni). Phase 3 clinical trials were presented outlining the treatment parameters, duration of treatment, and percent success rates for Harvoni. Also presented were FDA requirements for Phase 4 studies to be conducted to evaluate potential for carcinogenicity, follow up to evaluate development of resistance and long-term effectiveness, as well as safety and effectiveness in special patient populations. The Board also discussed a treatment algorithm that outlined key decision points for initiating and monitoring combination therapy including sofosbuvir treatment regimens.

The DUR Board recommended the following (3:26:52 - 3:36:05):

Activate Harvoni Coverage

Continue using clinical criteria* and/or point of service editing as approved at the September 2014 DUR Board meeting and implemented on 10/16/2014:

- FDA labeling and compendia supported use
- Prescriber experience and training
- Patient readiness and adherence
- Disease prognosis and severity

* Clinical criteria published in the October 2014 Medicaid Update (page 9 – 11)

Vote: support 7, oppose 0, abstain 1

5. Central Nervous Stimulants and Non-Stimulants utilized in the treatment of Attention Deficit Hyperactivity Disorder (ADHD) (Audio Cast Time 3:36:12 - 3:58:40)

Dr. Barbara Rogler presented a review of central nervous system stimulants and non-stimulants for the management of Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents. The Board discussed the prevalence of ADHD diagnosed in children and adolescents in the Medicaid population, inclusive of beneficiaries assigned to the fee for service and managed care plans. The Board discussed the percentage of children and adolescents in the Medicaid population receiving a stimulant or non-stimulant that did not have a FDA approved or compendia supported diagnosis.

The DUR Board recommended the following (3:53:45 - 3:58:40):

Confirm diagnosis for an FDA-approved or Compendia supported indication for beneficiaries less than 18 years of age who are starting stimulant or non-stimulant therapy

Absence of covered diagnosis in patient's claim history for beneficiaries not currently on therapy will require prescriber involvement.

Passed Unanimously

Prescriber involvement required when initiating stimulant therapy for beneficiaries less than 3 years of age.

Passed Unanimously

Prescriber involvement required when initiating non-stimulant therapy for beneficiaries less than 6 years of age.

Passed Unanimously

6. Prescriber Education Program (Audio Cast Time 3:58:52 – 04:24:45)

Dr. Diana Nagrecha presented an update of the Medicaid Prescriber Education Program focusing on the recently released treatment module for chronic non-cancer pain with a follow-up overview of recent initiatives. Dr. Nagrecha provided background information, beginning with a recommendation by the Drug Utilization Review Board for an educational intervention promoting appropriate use of opioid drugs in the treatment of pain. Key messages of the module were reviewed as well as specific treatment steps and considerations that should be part of a prescriber's methodology in non-cancer pain treatment. The module is available as a web based presentation (New York State Medicaid Prescriber Education Program) and provides continuing education credits for providers. Dr. Nagrecha also reviewed an updated Respiratory Syncytial Virus module as well as modules for diabetes and hypertension.

7. Respiratory Syncytial Virus (RSV) Prophylaxis – Updated American Academy of Pediatrics (AAP) Recommendations (Audio Cast Time 4:25:35 - 4:56:20)

Dr. Irene Hong presented a summary of the updated guidance from the American Academy of Pediatrics on RSV prophylaxis. The guidance is summarized in the Medicaid Prescriber Education Program (PEP). The Board discussed clinical criteria for NYS Medicaid Fee-For-Service and managed care beneficiaries. The Board discussed RSV virus characteristics, clinical presentation of the patient, risk factors and treatment management. A chronology of therapy as recommended by the American Academy of Pediatrics was discussed, concluding with the newly released recommendations for 2014. The 2014 recommendations were then reviewed with attention to beneficiary eligibility for prophylaxis. The Board was also informed of a recent change to fee-for service clinical criteria* based on the 2014 updated AAP guidance. The age maximum for prescriptions that do not require prior authorization was modified from children less than two years of age to children less than one year of age at the onset of RSV season.

**New York State Medicaid Update - August 2014 Volume 30 - Number 8*

http://www.health.ny.gov/health_care/medicaid/program/update/2014/aug14_mu.pdf

The DUR Board recommended the following (4:54:45 - 4:56:20):

Adopt clinical criteria supporting the 2014 American Academy of Pediatrics palivizumab guidelines to be implemented during the 2015 respiratory syncytial virus (RSV) season

Re-evaluation in the event that guidelines change prior to 2015 RSV season

Passed Unanimously

E. Final Comments and Adjournment

Audio Cast Time (4:56:33 - 4:57:00)

Janet Zachary-Elkind

John Naioti, RPh

Meeting adjourned at 3:30 PM