



## New York State Medicaid Drug Utilization Review (DUR) Board Meeting Summary for February 26, 2015

The Medicaid DUR Board met on Thursday, February 26, 2015 from 9:00 AM to 4:00 PM in Meeting Room 6, 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 01:10 - 3:45)

#### Department of Health

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

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

#### Drug Utilization Review Board

Lisa Anzisi, PharmD  
Nancy Balkon, PhD, NP  
Donna Chiefari, PharmD  
Marla Eglowstein, MD  
Renate Ignacio, MD

Jadwiga Najib, PharmD  
Michelle Rainka, PharmD  
James Saperstone, MD  
John Wikiera

#### SUNY – University at Buffalo

Holly Coe, PharmD  
Irene Reilly, PharmD

Barbara Rogler, PharmD, MS  
Safinaz Rahman, PharmD

#### Magellan Medicaid Administration

Eileen Zimmer, PharmD, MBA

### B. Old Business

(Audio Cast Time 03:45 - 04:43)

#### **Educational interventions**

At the November 20, 2014 Drug Utilization Review (DUR) Board meeting, the board recommended educational interventions for topics including metreleptin (Myalept), oral pollen/allergen extracts (Grastek, Oralair, Ragwitek), and second generation antipsychotics (SGA) utilized in the treatment of Major Depressive Disorder (MDD).

Information for Medicaid fee-for-service pharmacy prior authorization program updates including metreleptin and oral pollen/allergen extracts are included in the January 2015 issue of the Medicaid Update available at:

[http://www.health.ny.gov/health\\_care/medicaid/program/update/main.htm](http://www.health.ny.gov/health_care/medicaid/program/update/main.htm)

The second generation antipsychotic medications (SGAs) utilized in the treatment of major depressive disorder (MDD) intervention consisted of a targeted letter sent to 285 program providers on December 12, 2014. A copy of the letter was provided to board members at the meeting.

**C. Public Comment Period**

(Audio Cast Time 04:43 – 43:35)

The following people provided public comment to the DUR Board:

<u>Name</u>	<u>Affiliation</u>	<u>Agenda Topic</u>
1. Ali Toumadj, PharmD	Gilead Sciences	Cystic Fibrosis
2. John Nash, MSW	Albany Medical College	Cystic Fibrosis
3. Robert Kaslovsky, MD	Albany Medical College	Cystic Fibrosis
4. Jeanne Bruno-Joyce, PharmD	Novartis Pharmaceuticals	Cystic Fibrosis
5. Donna E. Goldman, MD	Genentech	Pulmonary Fibrosis
6. Gary Good, MD	Private Practice	Hepatitis C Virus
7. Ari L. Bunim, M.D.	New York Hospital Queens	Hepatitis C Virus
8. Lillian de Mauro	UHAP	Hepatitis C Virus
9. Ali Toumadj, PharmD	Gilead Sciences	Hepatitis C Virus
10. Jodi Walker, PharmD, BCPS	AbbVie	Hepatitis C Virus
11. Matthew Ben	Albany Gastroenterology	Hepatitis C Virus
12. Lillian de Mauro for Luis Santiago	ACT UP New York	Hepatitis C Virus

**D. Drug Utilization Reviews**

(Audio Cast Time 0:43:35 - 4:56:20)

1. Topical Antifungals for Onychomycosis

(ciclopirox - Penlac, efinaconazole - Jublia, tavaborole – Kerydin)

(Audio Cast Time 0:43:35 - 1:20:52)

Dr. Holly Coe presented a utilization review of topical antifungal agents used in the treatment of onychomycosis. The presentation identified the FDA approved topical products (ciclopirox, efinaconazole and tavaborole) and characterized their place in therapy. Dosage, administration, compendia support, pharmacology, safety and the place of these agents in the treatment of onychomycosis was outlined. A report on the utilization of these agents within the Medicaid fee-for-service (FFS) and Managed Care programs was presented, including both oral and topical dosage forms. Dr. Coe concluded by indicating that current guidelines for the treatment of onychomycosis recommend the use of oral agents prior to topical agents unless contraindicated or for specific use in certain types of fungal infections, and that

terbinafine tablets are considered first line therapy followed by itraconazole and griseofulvin.

The DUR Board recommended the following:

(Audio Cast Time 1:10:10 - 1:20:52)

Step therapy:

Trial with an oral antifungal agent\* prior to use of ciclopirox 8% solution

\*terbinafine (Lamisil) tablets; griseofulvin (Grifulvin V, Gris PEG) oral suspension, ultramicrotonized tablets micronized tablets; itraconazole (Sporanox, Onmel) tablets, oral solution

Override will require prescriber involvement

Passed: 8 in-favor, 1 against, 1 abstention

Step Therapy :

Trial with ciclopirox 8% solution prior to the use of other topical antifungals [efinaconazole (Jublia) or tavaborole (Kerydin)]

Override will require prescriber involvement.

Passed Unanimously

## 2. Cystine Depleting Agents

(cysteamine bitartrate - Cystagon, Procysbi)

(Audio Cast Time 1:20:52 - 1:38:38)

Dr. Holly Coe presented a review of the drug cysteamine bitartrate including the place in therapy of cysteamine immediate release (IR) and delayed-release (DR) products. Dr. Coe reviewed the disease state of nephropathic cystinosis after which she summarized drug therapy for this condition inclusive of FDA-approved products and indications, drug dosage and administration, pharmacology, and compendia review. Dr. Coe also reviewed adverse events, drug safety, and the suggested patient monitoring for both the immediate and delayed release products. Dr. Coe followed the clinical review with a utilization review of drug therapy within the FFS and managed Medicaid programs inclusive of beneficiary age. Dr. Coe concluded that both IR and DR cysteamine are FDA approved for nephropathic cystinosis, and that an international consensus document for treatment of this condition identifies that cysteamine is the mainstay of treatment, although use of the IR versus DR was not addressed. Clinical trials have shown similar efficacy between cysteamine IR and DR.

The DUR Board recommended the following:

(Audio Cast Time 1:37:30 - 1:38:38)

Confirm diagnosis for cysteamine immediate-release (IR) and delayed-release (DR) products for FDA approved indication: nephropathic cystinosis

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

Passed Unanimously

### 3. Hepatitis C Virus - Recently Approved Therapies/Preferred Drug Program Review

#### Hepatitis C Virus (HCV) – Direct Acting Antivirals (DAA)

Copegus (ribavirin), Harvoni (ledipasvir/sofosbuvir), Moderiba (ribavirin), Olysio (simeprevir), Rebetol (ribavirin), Ribapak (ribavirin), Ribasphere (ribavirin), ribavirin, Sovaldi (sofosbuvir), Victrelis (boceprevir), Viekira (ombitasvir/paritaprevir/ritonavir with dasabuvir)

(Audio Cast Time 2:00:45 - 3:42:20)

Dr. Barbara Rogler presented a drug update on the recent changes occurring in the treatment of Hepatitis C, including the place in therapy for the agents utilized for management of chronic hepatitis C (CHC) infection, recent updates to the American Association for the Study of Liver Disease (AASLD)/Infectious Disease Society of America (IDSA) guidance for the treatment of CHC, as well as a review of the recently approved product Viekira Pak (ombitasvir/paritaprevir/ritonavir and dasabuvir tablets). Chronic hepatitis C information was reviewed focusing on its prevalence, disease progression, and treatment goals. A treatment regimen flowchart was presented which highlighted the different pathways to be followed in the treatment of genotypes 1a and 1b. Dr. Rogler concluded by stating how judicious screening and monitoring are necessary to ensure safe and effective use in appropriate patients, and that clinical criteria for use by NY Medicaid FFS program will promote appropriate use and help to ensure successful outcomes.

Shelley Selph, M.D., of the Drug Effectiveness Review Project of the Oregon Health and Sciences University presented the comparative effectiveness drug class review of direct-acting antiviral agents (DAAs) for the treatment of Hepatitis C. The Key Questions identified by the project's participating organizations were presented, including comparison of benefits and harms of the different DAAs, consideration of HCV genotype, dose and duration of therapy, use in specific sub-populations and co-morbidities, disease severity, and evaluation of SVR and long-term outcomes. Research methods, inclusion and exclusion criteria, as well as strengths and limitations of the available evidence were discussed, including lack of direct head to head evidence between the DAAs. Some of the major findings reported included:

- In HCV genotype 1, inclusion of ribavirin in all-oral DAA regimens did not affect SVR, but harms were reduced without ribavirin.

- In treatment-naïve genotype 1 patients, 8 vs 12 weeks of ledipasvir/sofosbuvir did not affect SVR, but was associated with increased risk of relapse.
- No differences seen between population subgroups in effects of ribavirin, dose, or treatment duration on SVR; many subgroups were too small to detect differences between them.
- Stage of disease affected response to both the 3D regimen (ombitasvir/paritaprevir/ritonavir and dasabuvir) and ledipasvir/sofosbuvir in treatment-experienced patients or those with mixed treatment history. In patients with cirrhosis, shorter treatment durations were associated with lower SVR and/or relapse rates, while in those without cirrhosis duration did not affect benefits.
- Good correlation between SVR-12 and SVR-24 in oral and other regimens, but no evidence on SVR and any long term outcome in patients given DAAs.

Dr. Eileen Zimmer provided an overview of the NY Medicaid Preferred Drug Program (PDP) drug class for Hepatitis C Agents – Direct Acting Antivirals. This included a listing of the currently available products in the class, their mechanism of action, and use for the treatment of specific HCV genotypes. Other parameters identified in the overview of the direct acting antivirals were contraindications/warnings/adverse drug reactions, drug interactions, drug use in specific populations as well as drug dosage and administration including duration of therapy.

Dr. Robert Correia provided additional focus on specific information relevant to the review for the NY Medicaid program from the presentations addressing FDA labeled indications for use, drug interactions, guidelines and regimens, and comparative evidence. Additional consideration was identified relevant to specific HCV genotypes and special populations, inclusive of comorbidities and HCV/HIV co-infection. Dr. Correia identified how the level of available clinical evidence for these regimens has impacted what is considered best effective therapy, and how this may continue to evolve as new evidence on long-term outcomes continues to emerge. Dr. Correia concluded by clarifying the availability of medications in this class within the program.

At the conclusion of these presentations, the DUR Board adjourned to executive session. Following executive session, the board reconvened. Prior to voting, the standard clinical criteria utilized for prior authorization within the Preferred Drug Program were presented to the board.

Based on the clinical and financial information, the board recommended the following to the Commissioner of Health for final determination:

(Audio Cast Time 3:42:20 - 3:47:47)

Recommendations of the DUR Board	Commissioner's Final Determination
<p><u>Hepatitis C – Direct Acting Antivirals</u></p> <p>Preferred: ribavirin, Viekira*</p> <p>Non-Preferred: Copegus, Harvoni, Moderiba, Olysio, Rebetol, Ribapak, Ribasphere, Sovaldi, Victrelis</p> <p>*For Viekira in preferred status: Viekira to be excluded from the HCV clinical criteria addressing disease prognosis and severity.</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>

4. Inhaled Antibiotics for Cystic Fibrosis

(tobramycin inhalation - Bethkis, Kitabis, Tobi solution, Tobi Podhaler; aztreonam - Cayston)

(Audio Cast Time 3:47:47 - 4:22:10)

Dr. Irene Reilly presented the pathology and treatment of cystic fibrosis (CF) as well as microorganisms involved with infectious complications. Utilization was reviewed for the inhaled antibiotics used as adjunct treatment for patients with CF. Details of drug therapy were presented including compendia supported and investigational uses, pharmacology, drug dosing and drug safety. This included use of aerosolized or nebulized tobramycin and aztreonam across the entire Medicaid population (FFS and Managed Care). Utilization review evaluated drug quantity and cost, and compliance with recommended dosing regimens by Medicaid beneficiaries. With respect to these parameters Dr. Reilly concluded in her report that most utilization appeared appropriate based upon frequency, quantity and duration, but only about half of the utilizing beneficiaries had a diagnosis of CF on record.

The DUR Board recommended the following: (Audio Cast Time 4:22:10 - 4:24:25)

<p>For inhaled aztreonam and tobramycin:</p> <p>Confirm diagnosis for the FDA-approved indication: Cystic Fibrosis</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>Quantity limit: Aztreonam inhalation solution (Cayston®):</p> <ul style="list-style-type: none"><li>• 3 ampules (3 ml.) per day</li><li>• 84 ampules (84 ml.) per 56 day regimen (28 days on-28 days off)</li></ul> <p style="text-align: right;">Passed Unanimously</p>
<p>Quantity limit: Tobramycin inhalation solution (Bethkis®, Tobi®, Kitabis Pak™):</p> <ul style="list-style-type: none"><li>• 2 ampules (8 ml. Bethkis®, 10 ml. Tobi®, Kitabis Pak™) per day</li><li>• 56 ampules (224 ml. Bethkis®, 280 ml. Tobi®, Kitabis Pak™) per 56 day regimen (28 days on-28 days off)</li></ul> <p style="text-align: right;">Passed Unanimously</p>
<p>Quantity limit: Tobramycin capsules with inhalation powder (Tobi® Podhaler™):</p> <ul style="list-style-type: none"><li>• 8 capsules per day</li><li>• 224 capsules per 56 day regimen (28 days on-28 days off)</li></ul> <p style="text-align: right;">Passed Unanimously</p>

5. Agents for Pulmonary Fibrosis  
(nintedanib - Ofev, pirfenidone - Esbriet)

(Audio Cast Time 4:24:25 - 4:43:20)

Dr. Irene Reilly presented a review of the two drugs used to treat pulmonary fibrosis, describing idiopathic pulmonary fibrosis and the corresponding drugs approved for treatment of this condition. Pharmacology, dosage and administration, drug safety and literature support specific to identifying the place in therapy of these agents was outlined for both drugs. Investigational use of each drug was mentioned as well as lack of compendia support for these uses. Dr. Reilly summarized that neither drug

has been shown to improve lung function over baseline, available data suggest efficacy primarily by decrease in rate of decline of lung function over time, and that effect on survival with treatment of either drug is inconclusive.

The DUR Board recommended the following: (Audio Cast Time 4:42:35 - 4:43:20)

Confirm diagnosis for the FDA-approved indication: Treatment of idiopathic pulmonary fibrosis (IPF)

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

Passed Unanimously

## E. DUR Program Updates

### 1. Retrospective Evaluation of Clinical Editing – Metformin

(Audio Cast Time 1:38:38 - 2:00:14)

Dr. Barbara Rogler presented a retrospective evaluation of utilization of metformin as a first-line treatment for diabetes across the Medicaid population including (FFS) and managed care organizations (MCOs) before and after the clinical step edit was implemented (November 2012). This edit requires a trial with metformin with or without insulin prior to initiating other antidiabetic agents for FFS beneficiaries with type-2 diabetes mellitus (T2DM) in most cases. The intervention has resulted in increased utilization of metformin as initial treatment in the FFS population. This trend was also seen in the managed care population. The recommendation to the board was to continue the clinical edit requiring a trial with metformin with or without insulin prior to initiating other antidiabetic agents (unless contraindication is documented) in FFS beneficiaries with T2DM.

### 2. Retrospective Evaluation of Clinical Editing – Opioids

(Audio Cast Time 4:43:20 - 5:02:00)

Dr. Barbara Rogler presented an analysis to evaluate the utilization of short acting opioids (SAO) for the management of acute and chronic non-cancer pain (CNCP) for NYS Medicaid (FFS) or managed care organizations (MCO). Reviewed were the various clinical edits and other factors implemented over time, including the NYS Bureau of Narcotic Enforcement I-STOP program, and how they impacted that utilization. These edits included the limit of 4 opioid prescriptions per 30 days, quantity limits on morphine and congeners, 90-day duration limits on short-acting opioids and 15-day duration limits for opioid naïve patients. Conclusions from the analysis included:

- The combination of pharmacy point-of-service (POS) clinical edits and programs have helped to slow the overall rate of growth of opioid utilization.
- POS clinical edits resulted in a decline in the percentage of beneficiaries that were noncompliant.
- Based on the results of this evaluation the current SAO pharmacy clinical edits should remain unchanged.

### 3. Prescriber Education Program

(Audio Cast Time 5:02:00 - 5:11:50)

Dr. Safinaz Rahman presented an overview of the activities of the New York State Medicaid Prescriber Education Program (NYSMPEP). The overview included descriptions of current educational modules for hypertension, diabetes, respiratory syncytial virus (RSV) and treatment of chronic non-cancer pain (CNCP). NYSMPEP also conducted physician provider visits in the New York City region, Western NY and Upstate NY that included grand rounds, one on one visits and small group presentations.

### F. Final Comments and Adjournment

(Audio Cast Time 5:11:50 - 5:12:31)

Janet Zachary-Elkind  
John Naioti, RPh

### Meeting adjourned at 3:50 PM

### G. Commissioner's Final Determinations

The impact of the final determinations on the PDP is as follows:

#### State Public Health Population:

- o Minimal impact on Medicaid fee-for-service beneficiaries, as a large majority of beneficiaries would meet the criteria for preferred products. Non-preferred products remain available with prior authorization. No impact on Medicaid managed care beneficiaries.

#### Program Providers:

- o Streamlined clinical criteria for Viekira in preferred status will have positive impact on prescribers utilizing preferred HCV DAAs. Prescribers will need to proceed through the standard clinical criteria and prior authorization process when ordering non-preferred products in the HCV DAA therapeutic class.

#### State Health Program:

- o Savings will be achieved through utilization of more cost effective products in the therapeutic class consequential to the receipt of supplemental rebates.