



New York State Medicaid Drug Utilization Review (DUR) Board Meeting Summary for September 15, 2016

The Medicaid DUR Board met on Thursday, September 15, 2016 from 9:00 AM to 4:00 PM 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: https://www.health.ny.gov/events/webcasts/2016/2016-09-15_dur.htm

A. Welcome and Introductions

(Audio Cast Time 00:18 - 02:08)

Department of Health

Janet Zachary-Elkind

Robert Correia, PharmD

Douglas Fish, MD

Anthony Merola, RPh, MBA

John Naioti, RPh

Alda Osinaga, MD

Robert Sheehan, RPh

Monica Toohey, RPh

DUR Board

Lisa Anzisi, PharmD

Nancy Balkon, PhD, NP

Donna Chiefari, PharmD

Marla Eglowstein, MD

James Hopsicker, RPh, MBA

Jadwiga Najib, PharmD

Michelle Rainka, PharmD

James Saperstone, MD

SUNY – University at Buffalo

Holly Coe, PharmD

Terry Dunn, PharmD

Barbara Rogler, PharmD, MS

Magellan Medicaid Administration

Eileen Zimmer, PharmD, MBA

B. Public Comment Period

(Audio Cast Time 02:08 - 00:47:00)

The following speakers provided public comment to the board:

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|------------------------------|-----------------------|---------------------------|
| 1. Franco Casagrande, PharmD | Abbvie | Hepatitis C Agents – DAAs |
| 2. Jeffery Olson, PharmD | Gilead Sciences, Inc. | Hepatitis C Agents – DAA |
| 3. Beth D'Ambrosio, PharmD | Novartis Pharm. Corp. | ARBs Combinations |
| 4. Jeffery S. Olson, PharmD | Gilead Sciences | PAH Agents - Oral |

5.	Stephen C. Hull, MD	Supernus Pharm., Inc.	Anticonvulsants - Second Generation
6.	Doug Plessinger, RPh	Apexia	Anticonvulsants - Second Generation
7.	Jason T. Moyer, PhD	UCB, Inc.	Anticonvulsants - Second Generation
8.	Uri Dreckshage, BS	Sanofi-Genzyme Corp.	Multiple Sclerosis Agents
9.	Franco Casagrande, PharmD	Abbvie	Multiple Sclerosis Agents
10.	Pamela Sardo, PharmD,	Avanir Pharmaceuticals	Serotonin Receptor Agonists
11.	Beth D'Ambrosio, PharmD	Novartis Pharm. Corp.	Immunomodulators, Systemic
12.	Daniel Flores, PharmD, MS	AMGEN Scientific Affairs	Immunomodulators, Systemic
13.	Maria Cannito, PharmD, MS	Pfizer	Immunomodulators, Systemic
14.	April W. Johnston, PharmD	Eli Lilly and Company	Immunomodulators, Systemic
15.	Franco Casagrande, PharmD	Abbvie	Immunomodulators, Systemic
16.	Paul McDermott, RPh, MBA	Celgene Corporation	Immunomodulators, Systemic
17.	Adam Bloomfield, MD	AstraZeneca	Synagis

C. Preferred Drug Program (PDP) Reviews

Barbara Rogler, PharmD, MS
Eileen Zimmer, PharmD, MBA
Robert Correia, PharmD

1. Hepatitis C Agents – Direct Acting Antivirals (Audio Cast Time 0:47:12)

- New Products: Epclusa (sofosbuvir and velpatasvir), Viekira XR (ombitasvir/paritaprevir/ritonavir/dasabuvir)
- New Formulations
- Expanded Indications
- Label Revisions
- Clinical Trials
- Practice Guidelines - American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) – July 2016

2. ARBs Combination (Audio Cast Time 1:12:15)

- New Products: Entresto® (sacubitril/valsartan), Edarbyclor (azilsartan/chlorthalidone), Byvalson™ (nebivolol/valsartan)
- Label Revisions

3. Pulmonary Arterial Hypertension (PAH) Agents, Oral (Audio Cast Time 1:27:35)

- New Products: Uptravi® (selexipag)
- Expanded Indications
- Label Revisions
- Practice Guidelines- American Heart Association and American Thoracic Society – November 2015

4. Anticonvulsants - Second Generation (Audio Cast Time 1:35:08)

- New Products: Spritam® (levetiracetam), Briviact® (brivaracetam)
- New Formulations
- Expanded Indications
- New clinical information: FDA communications
- Label Revisions
- Practice Guidelines - American Academy of Neurology (AAN) and the American Epilepsy Society – May 2015, American Pain Society – February 2016

5. Multiple Sclerosis Agents (Audio Cast Time 1:43:50)

- New Products: Glatopa™ (glatiramer), Zinbryta™ (daclizumab)
- New clinical information: FDA Communication
- Label Revisions
- Manufacturer information

6. Serotonin Receptor Agonists (Triptans) (Audio Cast Time 1:51:55)

- New Products: Zembrace™ SymTouch™ (sumatriptan) injection, Onzetra Xsail
- New Indications

7. Immunomodulators, Systemic (Audio Cast Time 1:57:15)

- New Products: Taltz® (ixekizumab)
- New Formulations
- New Indications
- Label Revisions
- Practice Guidelines - American College of Rheumatology (ACR) – November 2015

D. Executive Session (Recess to Excessive Session Audio Cast Time 2:07:23)

The board recessed the public session at 11:30 AM to go into executive session for review of financial information relating to each of the PDP therapeutic classes under review. No official action was taken in the executive session. The board reconvened to the public session at 1:00 PM.

E. DUR Board Preferred Drug Program Recommendations

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

Recommendations of DUR Board	Commissioner's Final Determination
<p>Hepatitis C Agents - Direct Acting Antivirals Audio Cast Time 2:07:45</p> <p>Preferred Epclusa (for genotypes 2 & 3), Harvoni, ribavirin, Technivie, Viekira Pak, Viekira XR, Zepatier</p> <p>Non-preferred Copegus, Daklinza, Moderiba, Olysio, Rebetol, Ribasphere, Sovaldi</p> <p style="text-align: right;">Passed unanimously</p> <p>HCV DAA clinical criteria:</p> <ul style="list-style-type: none"> • FDA labeling and compendia supported use. • Prescriber experience and training. • Patient readiness and adherence. 	<p>Approved as Recommended</p>
<p>ARB Combinations Audio Cast Time 2:11:25</p> <p>Preferred Exforge HCT, losartan/HCTZ, valsartan/amlodipine, valsartan/amlodipine/HCTZ, valsartan/HCTZ</p> <p>Non-preferred Atacand HCT, Avalide, Azor, Benicar HCT, Byvalson, candesartan/HCTZ, Diovan HCT, Edarbyclor, Entresto*, Exforge, Hyzaar, irbesartan/HCTZ, Micardis HCT, telmisartan/amlodipine, telmisartan/HCTZ, Tribenzor, Twynsta</p> <p style="text-align: right;">Passed unanimously</p> <p>* Clinical Criteria: Patient has chronic symptomatic HFREF (NYHA class II or III), who can tolerate an ACE or ARB (and transition to the non-preferred product is warranted to produce the desired health outcome).</p>	<p>Approved as Recommended</p>
<p>Pulmonary Arterial Hypertension (PAH) Agents, Oral Audio Cast Time 2:12:46</p> <p>Preferred Letaris, Tracleer, Orenitram</p> <p>Non-preferred Adempas, Opsumit, Uptravi</p> <p style="text-align: right;">Passed Unanimously</p>	<p>Approved as Recommended</p>

<p>Anticonvulsants – Second Generation Audio Cast Time 2:13:16</p> <p>Preferred</p> <p>felbamate, gabapentin capsule, gabapentin solution, Gabitril 2mg & 4mg, lamotrigine, levetiracetam, levetiracetam ER, Lyrica, topiramate, zonisamide</p> <p>Non-preferred</p> <p>Banzel, Briviact, Felbatol, Fycompa, gabapentin tab, Gabitril 12mg & 16mg, Keppra, Keppra XR, Lamictal, Lamictal ODT, Lamictal XR, lamotrigine ODT, lamotrigine ER, Neurontin, Onfi, Potiga, Qudexy XR, Sabril, Spritam, tiagabine, Topamax, topiramate ER, Trokendi XR, Vimpat, Zonegran</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Multiple Sclerosis Agents Audio Cast Time 2:13:48</p> <p>Preferred</p> <p>Avonex, Betaseron, Copaxone 20 mg/ml, Gilenya*</p> <p>Non-preferred</p> <p>Aubagio, Copaxone 40 mg/ml, Extavia, Glatopa, Plegridy, Rebif, Tecfidera, Zinbryta</p> <p>*Requires a trial with a preferred injectable product.</p> <p>8 in favor, 1 opposed, no abstentions</p> <p>Note - One board member recommended that Aubagio be moved to preferred status but the motion was not seconded by the board.</p>	<p>Approved as Recommended</p>
<p>Serotonin Receptor Agonists (triptans) Audio Cast Time 2:16:00</p> <p>Preferred</p> <p>Imitrex Kit (cartridge, pen), rizatriptan, sumatriptan (spray, tab, vial)</p> <p>Non-preferred</p> <p>almotriptan, Amerge, Axert, Frova, frovatriptan, Imitrex (spray, tab, vial), Maxalt, naratriptan, Onzetra Xsail, Relpax, Sumavel DosePro, sumatriptan kit (cartridge, pen), Treximet, Zembrace Sym Touch, zolmitriptan, Zomig</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>

Immunomodulators – Systemic Audio Cast Time 2:16:30 Preferred Enbrel, Humira Non-preferred Actemra (sub Q), Cimzia, Cosentyx, Kineret, Orencia (sub Q), Otezla, Simponi, Stelara, Taltz, Xeljanz, Xeljanz XR Passed Unanimously	Approved as Recommended
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F. Drug Utilization Reviews (DUR)

(Audio Cast Time 2:17:00)

1. Gabapentin

(Audio Cast Time 2:17:30 - 3:10:45)

A review of gabapentin was presented, the purpose of which was to evaluate utilization of gabapentin across the entire Medicaid program, fee-for-service (FFS) and Managed Care (MC). Background information included case reports of abuse and misuse of the product, population surveys that were conducted suggesting potential for abuse/misuse of gabapentin within those populations, as well as reports of gabapentin abuse/misuse among patients having a history of substance abuse. Data showing the overall utilization of gabapentin within the Medicaid FFS and Medicaid MC programs was presented along with FDA approved and compendia supported use as well as non-supported use of this agent as found within the two programs. Dosing parameters used for approved FDA/Compendia use in comparison to dosing in non-supported use were also reviewed. Utilization statistics addressing indications and dosages were presented for both Medicaid FFS and MC programs.

Potential program actions to address retrospective utilization outliers were discussed. A Department of Health recommendation of an educational letter to targeted prescribers of gabapentin regarding the FDA-approved/compendia-supported diagnoses was tabled. It was determined that more research on reasons for utilization would be appropriate before developing specific provider communications.

The DUR Board recommended the following:

Dose limit: Based on maximum daily dose of 3600 mg. per day Passed Unanimously

2. Injectable Anticoagulants:

(Audio Cast Time 3:10:45 - 3:26:40)

A review of injectable anticoagulants was presented, the purpose of which was to examine the utilization of the injectable anticoagulants across the Medicaid FFS and

MC programs. The review included a review of products, their indications and administered doses for this class of agents. Utilization statistics were presented including claim volume in relationship to the duration of therapy in conjunction with approved and non-approved FDA or compendia supported diagnosis.

The information presented noted that the majority of claim volume was represented by the drug enoxaparin. In addition, the review included FDA/compendia supported and non-supported conditions for which utilization was equal to or less than 30 days as well as therapy durations in excess of 30 days.

The DUR Board recommended the following:

Duration Limit: No more than 30 days for members initiating Injectable Anticoagulant therapy <p style="text-align: right;">Passed Unanimously</p>
For patients requiring longer than 30 days of therapy: Documentation of FDA or Compendia-supported indication Absence of covered diagnosis in patient's claim history requires prescriber involvement <p style="text-align: right;">Passed Unanimously</p>

3. Products for Irritable Bowel Syndrome (IBS) (Audio Cast Time 3:26:40 - 4:12:00)

A review of IBS pharmacological therapies was presented. The first review focused on IBS associated with constipation (IBS-C), and evaluated the utilization of agents across the Medicaid FFS and Managed Care programs. The review included the guidelines of the World Gastroenterological Organization as well as the American Gastroenterological Association for the treatment of IBS-C. The review also incorporated an evaluation of utilization in relation to existing clinical criteria currently in place for linaclotide and lubiprostone.

The second part of the review focused on IBS associated diarrhea (IBS-D), and also evaluated the utilization of these agents across the Medicaid FFS and Managed Care programs. The review included the guidelines of the World Gastroenterological Organization as well as the American Gastroenterological Association for the treatment of IBS-D. The utilization review focused on the following drugs: alosetron, eluxadoline and rifaximin. The data presented showed that the majority of utilization was for rifaximin. The Department provided an overview of previously approved clinical criteria for both IBS-C and IBS-D and noted that these formerly (board) approved recommendations did not require any further board action.

The DUR Board recommended the following:

No change to edits currently in place for linaclotide and lubiprostone per previous board review and approval:

- Step therapy prior to use for IBS-C
- Duration and quantity limits
- Diagnosis requirement to ensure utilization for the FDA-approved or compendia-supported indications

Absence of covered diagnosis in patient's claim history requires prescriber involvement

Passed Unanimously

No change to edits currently in place for rifaximin for IBS-D per previous Board review and approval:

- Step therapy prior to use for Traveler's Diarrhea
- Frequency, duration and quantity limits
- Diagnosis requirement to ensure utilization for the FDA-approved or compendia-supported indications

Absence of covered diagnosis in patient's claim history requires prescriber involvement

Passed Unanimously

Diagnosis requirement: alosetron -

For adult females with severe IBS-D lasting ≥ 6 months who have failed other treatments

Absence of covered diagnosis in patient's claim history requires prescriber involvement

Passed Unanimously

Step Therapy: alosetron -

Trial with both eluxadolone AND rifaximin prior to using alosetron

Passed Unanimously

Diagnosis requirement: eluxadoline -

Adults with IBS-D

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

Passed Unanimously

G. Clinical Editing Reviews

(Audio Cast Time 4:12:00 - 4:47:20)

Based on previous recommendations of the board, utilization information before and after implementation of clinical criteria and/or intervention was presented for the following drugs/drug classes:

1. sodium oxybate (Xyrem)
2. tasimelteon (Hetlioz)
3. memantine ER (Namenda XR)
4. tetrabenazine (Xenazine)
5. lomitapide (Juxtapid) and mipomersen (Kynamro)
6. palivizumab (Synagis)
7. serotonin receptor agonists (Tryptans)

H. Final Comments and Adjournment

(Audio Cast Time 4:47:20 - 4:50:14)

Janet Zachary-Elkind
Anthony Merola, RPh, MBA
John Naioti, RPh

Meeting adjourned at 4:00 PM

I. Commissioner Final Determinations

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

State Public Health Population:

- Minimal effect on Medicaid beneficiaries, as a large majority of beneficiaries currently utilize preferred products. Non-preferred products remain available with prior authorization.

Program Providers:

- No impact on prescribers when utilizing preferred products. Prescribers, or their agents, will need to initiate the prior authorization process when ordering non-preferred products.

State Health Program:

- Annual gross savings associated with these therapeutic classes under the PDP are estimated at \$4.4 million. The savings are achieved through changes in utilization including the receipt of supplemental rebates from pharmaceutical manufacturers.