



New York State Medicaid Drug Utilization Review (DUR) Board Meeting Summary for November 5, 2020

The Medicaid DUR Board met on Thursday, November 5, 2020 from 9:00am to 4:00pm. In consideration of COVID-19 guidelines, the meeting was held virtually and available for public viewing by way of a live audio-video webcast.

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 Introduction

Approx. Webcast Time 00:00:24

Department of Health

Douglas Fish, MD – DUR Board Chairperson

Robert Correia, PharmD

Anthony Merola, RPh, MBA

Robert Sheehan, RPh

Monica Toohey, RPh

Janet Zachary-Elkind

DUR Board Members

Lisa Anzisi, PharmD

Donna Chiefari, PharmD

Marla Eglowstein, MD

James Hopsicker, RPh, MBA

Renante Ignacio, MD

Jacqueline Jacobi, RPh

Jill Lavigne, PhD, MS, MPH

Peter Lopatka, FSA

Jadwiga Najib, PharmD

John Powell

Michael Pasquarella, PharmD

Casey Quinn, PhD

Asa Radix, MD

Tara Thomas, RPh, MBA, MPA

Deborah Wittman, PharmD, MBA

Jamie Wooldridge, MD

Magellan Medicaid Administration

Eileen Zimmer, PharmD, MBA

SUNY – University at Buffalo

Holly Coe, PharmD

Barbara Rogler, PharmD, MS

B. Public Comment Period

Approx. Webcast Time 00:10:24

The following speakers provided public comment to the DUR Board:

- 1. Beth D'Ambrosio, PharmD Novartis ARB Combinations
2. Tammy Martin, BSN, MS Biohaven Medical Affairs Antimigraine Agents-Acute
3. Maria Dolgovina Private Practice Antimigraine Agents-Acute
4. Patricia Jacob, PharmD Abbvie Antimigraine Agents-Acute

5. Elizabeth Lubelczyk, PharmD	Eli Lilly	Antimigraine Agents-Acute
6. Melissa Winget, PhD	Sunovian	Antipsychotics-2 <sup>nd</sup> Generation
7. Brian Joseph, MD*	Private Practice	Antipsychotics-2 <sup>nd</sup> Generation
*Audio connectivity issue. Therefore, the DUR Board was referred to the written testimony.		
8. John Donovan, RPh	BMS	Multiple Sclerosis
9. Beth D'Ambrosio, PharmD	Novartis	Multiple Sclerosis
10. Jean McGrath Brodeur, PharmD	Pfizer	Immunomodulators-Systemic
11. Daniel Shan, PharmD	UCB	Immunomodulators-Systemic
12. Elizabeth Lubelczyk, PharmD	Eli Lilly	Immunomodulators-System
13. Sarah Hnath, PT, DPT	Abbvie	Immunomodulators-Systemic
14. Dan Flores	Amgen	Immunomodulators-Systemic
15. Howard Blumstein, MD, FACR	Private Practice	Immunomodulators-Systemic

### C. Preferred Drug Program (PDP) Clinical Review

Approx. Webcast Time 00:55:28

Eileen Zimmer, PharmD, MBA  
Holly Coe, PharmD  
Robert Correia, PharmD

#### 1. ARB Combinations

- New indication in pediatrics – Entresto (sacubitril-valsartan).
- FDA communication on hydrochlorothiazide containing combinations.
- Clinical review revealed no significant new evidence in overall superiority of any of the drugs in this class since last review.

#### 2. Antimigraine Agents – Acute Treatment

- New products: Nurtec ODT (rimegepant), Ubrelvy (ubrogepant), Reyvow (lasmiditan).
- Consider changes to the quantity limit edits on rizatriptan and eletriptan.
- Recommend future edit evaluation of new antimigraine agents (lasmiditan-Reyvow, rimegepant-Nurtec OTC, and ubrogepant-Ubrelvy).
- No new comparative evidence found or provided to suggest overall advantage for any one drug product in this class.

#### 3. Antipsychotics – Second Generation

- New product – Caplyta (lumateperone).
- New formulation – Secuado (asenapine).
- FDA safety communication – clozapine.
- Guideline update – schizophrenia treatment update.
- Key Label revisions – Abilify, Rexulti, Risperdal, Seroquel/XR, Zyprexa, Zydis ODT.
- The focus on this class is on balancing perceived efficacy with risk of adverse outcomes between drugs. No one drug can be considered to have overall superiority.

#### 4. Multiple Sclerosis

- New products – Vumerity (diroximal fumerate), Mavenclad (cladribine), Zeposia (ozanimod), Mayzent (siponimod), Bafiertam (monomethyl fumerate), Kesimpta (ofatumumab).

- Key Label revisions – Copaxone (glatiramer), Gilenya (fingolimod), Tecfidera (dimethyl fumarate).
- No new evidence that any of these agents are better for all patients, with each demonstrating favorable efficacy, tolerability, or benefits over risk for different patients.

5. Gastrointestinal Antibiotics

- New indications – Vancocin (vancomycin), Dificid (fidaxomicin).
- Key Label revisions – Vancocin, metronidazole.
- There are varied and multiple indications for the drugs in this class, superiority of any one agent in this class cannot be determined.

6. Immunomodulators - Systemic

- New products – Rinvoq (upadacitinib).
- New indications – Stelara (ustekinumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Xeljanz XR (tofacitinib).
- New practice guidelines – ustekinumab, tofacitinib, early use of biologics.
- Key label revisions – Tremfya (guselkumab), Orencia (abatacept), Cosentyx (secukinumab).
- Major identifying points of members in this class were identified, including proposed mechanisms of action and dosage forms.
- The overall evidence is consistent with previous reviews of this class.

**D. Executive Session (PDP Financial Reviews)**

The DUR Board recessed to executive session at 11:15pm. and reconvened to the public session at 12:45pm.

**E. DUR Board PDP Recommendations**

Approx. Webcast Time 02:11:38

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

Recommendations of the DUR Board	Commissioner Final Determination
<p><b>1. ARB Combinations</b></p> <p><b>Preferred:</b> amlodipine/valsartan, amlodipine/valsartan/HCTZ, Entresto, Exforge HCT, losartan/HCTZ, valsartan/HCTZ</p> <p><b>Non- Preferred:</b> amlodipine/olmesartan, amlodipine/olmesartan/HCTZ, amlodipine/telmisartan, Atacand HCT, Avalide, Azor, Benicar HCT, candesartan/HCTZ, Diovan HCT, Edarbyclor, Exforge, Hyzaar, irbesartan/HCTZ, Micardis HCT, olmesartan/HCTZ, telmisartan/HCTZ, Tribenzor</p> <p>Vote: 17 yes, 0 no, 0 abstentions</p>	<p>Approved as Recommended</p>

<p><b>2. Antimigraine Agents – Acute Treatment</b></p> <p><b>Preferred:</b> rizatriptan, sumatriptan</p> <p><b>Non-Preferred:</b> almotriptan, Amerge, eletriptan, Frova, frovatriptan, Imitrex, Maxalt, Maxalt MLT, naratriptan, Nurtec ODT, Onzetra Xsail, Relpax, Reyvow, sumatriptan-naproxen, Tosymra, Treximet, Ubrelvy, Zembrace Sym Touch, zolmitriptan, Zomig, Zomig ZMT</p> <p>Vote: 17 yes, 0 no, 0 abstentions</p>	<p>Approved as Recommended</p>
<p><b>3. Antipsychotics – Second Generation</b></p> <p><b>Preferred:</b> aripiprazole tablet, clozapine tablet, Latuda, olanzapine tablet, quetiapine, quetiapine ER, risperidone, Saphris, ziprasidone</p> <p><b>Non-Preferred:</b> Abilify tablet, aripiprazole (ODT, solution), clozapine ODT, Caplyta, Clozaril, Fanapt, FazaClo, Geodon, Invega, Nuplazid, olanzapine ODT, paliperidone ER, Rexulti, Risperdal, Secuado Patch, Seroquel, Seroquel XR, Versacloz, Vraylar, Zyprexa, Zyprexa Zydis</p> <p>Vote: 17 yes, 0 no, 0 abstentions</p>	<p>Approved as Recommended</p>
<p><b>4. Multiple Sclerosis Agents</b></p> <p><b>Preferred:</b> Avonex, Betaseron, Copaxone 20 mg/ml, Gilenya, Tecfidera</p> <p><b>Non-Preferred:</b> Aubagio, Bafiertam, Copaxone 40 mg/ml, Extavia, glatiramer, dimethyl fumarate DR, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Rebif, Vumerity, Zeposia</p> <p>Vote: 17 yes, 0 no, 0 abstentions</p>	<p>Approved as Recommended</p>
<p><b>5. Gastrointestinal Antibiotics</b></p> <p><b>Preferred:</b> Firvanq, metronidazole tablets, neomycin, vancomycin capsules</p> <p><b>Non-Preferred:</b> Dificid, Flagyl, metronidazole capsules, paromomycin, tinidazole, vancomycin solution, Vancocin, Xifaxin</p> <p>Vote: 17 yes, 0 no, 0 abstentions</p>	<p>Approved as Recommended</p>
<p><b>6. Immunomodulators – Systemic</b></p> <p><b>Preferred:</b> Cosentyx, Enbrel, Humira</p> <p><b>Non-Preferred:</b> Actemra, Benlysta, Cimzia, Ilumya, Kevzara, Kineret, Olumiant, Orenzia, Otezla, Rinvoq ER, Siliq, Simponi, Skyrizi, Stelara, Taltz, Tremfya, Xeljanz, Xeljanz ER</p> <p>Vote: 17 yes, 0 no, 0 abstentions</p>	<p>Approved as Recommended</p>

Barbara Rogler, PharmD, MS

1. Opioids used for the treatment of acute pain and morphine milligram equivalent (MME) parameters.

An analysis was presented that evaluated the impact of the DUR Board established POS safety edit for the initial management of acute pain in opioid naïve members.

A retrospective analysis of the effectiveness of the current  $\leq 90$  MME/day point-of-service (POS) edit was presented which included the period (July 1, 2019 to September 30, 2019) before the institution of the MME edit and after (January 1, 2020 to March 31, 2020) the edit was implementation. The analysis included members of the Fee for Service and Medicaid Managed (Care FFS+MCO) programs. Claims excluded from the analysis were; claims for products use in the treatment of substance use disorders, claims for Schedule V controlled substances, claims for liquid and injectable opioids (only solid formulations were included i.e. patches, tablets, capsules and films). Members diagnosed with Cancer or Sickle Cell disease (SCD), receiving hospice services, or without continuous enrollment during the analysis period were excluded as were duplicate pharmacy claims (defined as claims for the same member, receiving the same national drug code and prescription number and refill code). Limitations to the analysis were also identified.

For opioid naïve members it was found, when comparing pre to post implementation, there was a 10.2% reduction in the total number of members (FFS+MCO) receiving an opioid, a 12.7% decline in the number of opioid-naïve members initiating opioid therapy for the management of acute pain, and a 0.2% increase in the number of opioid naïve members who initiated opioid therapy at a MME of  $<50$ .

The utilization review established that the edit of  $\leq 90$  MME had been effective and concluded that reducing the MME from  $\leq 90$  to  $\leq 50$  would have minimal effect on opioid naïve members initiating opioid therapy for the management of acute pain. Consistent with other opioid POS safety edits, members with a diagnosis of cancer or SCD and members receiving hospice care would be excluded.

After reviewing the data from the utilization review, the DUR Board took the following action:

<b>Recommendation of the DUR Board</b>
<p><b>Drug Utilization Review: Opioids used for the treatment of acute pain and morphine milligram equivalent (MME) parameters</b></p> <p>Recommendation: For opioid-naïve patients: Prior authorization is required when initiating therapy with a short-acting opioid (SAO) at equal to or greater than (<math>\geq</math>) 50 morphine milligram equivalents (MME) per day.</p> <p>Note: Reduction from <math>\geq 90</math> MME per day Exceptions are patients with cancer, Sickle Cell Disease or receiving hospice care</p> <p>Vote: 17 yes, 0 no, 0 abstentions</p>

## 2. Long Acting Injectable Antipsychotic utilization as related to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act.

The review examined selected injectable antipsychotics and their utilization across the entire Medicaid population, including the fee-for-service (FFS) program and managed care organizations (MCOs). Utilization data was reviewed during State Fiscal Year (SFY) 2019 and the first six months of 2020. The purpose was to characterize the utilization of long-acting injectable (LAI) antipsychotics across each pharmacy management entity (FFS and MCO), as a component of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).

Methodology used in the report was presented which identified inclusion and exclusion criteria. The following areas were addressed in the presentation; a review of available first-and-second generation LAI antipsychotics as well as their FDA approved indications. Background information on the use of these agents was indicated primarily for adults only and that LAI antipsychotic agents used in pediatric patients (age<18) has not been established (fluphenazine decanoate is contraindicated in pediatrics <12 years), that manufacturers of all LAI antipsychotics recommend administration by health care professionals (with the exception of fluphenazine decanoate), and finally, tolerability with an oral antipsychotic is recommended prior to the initiation of a LAI antipsychotic.

Utilization data was presented on the use of injectable antipsychotics within the NY FFS Medicaid Program as well as that of the Medicaid MCO plans. Overall utilization of LAI antipsychotics noted were the following:

- Approximately 62% of those members (FFS+MCO) initiating LAI antipsychotic therapy had also used an oral antipsychotic at some point during the analysis period.
- The majority of members (63.5% in 2019 and 63.7% in 2020) utilizing LAI antipsychotics were male.
- The most common age range for members utilizing LAI antipsychotics in the overall population was 18-30 years.
- A small percentage of the total number of patients receiving LAI antipsychotics were <18 years of age (0.3%)
- Members in the overall population used as many as 4 different LAI antipsychotics during SFY 19 or the first 6 months of SFY 20. However, the overwhelming majority had claims for only one, specific LAI during each period.
- Concurrent use of 2 different LAI antipsychotic products for  $\geq 90$  days and  $\geq 180$  days was similar and low across the populations (below 1%).
- Concurrent use of LAI and oral antipsychotic drugs for  $\geq 90$  days was observed in 15.8% of FFS+MC members and 14.8% of FFS only members.
- In comparison, concurrent use of LAI and oral antipsychotic drugs for  $\geq 180$  days was observed in 7.4% of FFS+MC members and 6.4% in FFS members.

The evidence to support concurrent use of oral or non-injectable antipsychotics with LAI antipsychotics is limited. It was recommended that the DUR Board continue to monitor and manage the use of oral and LAI antipsychotics in the pediatric population. Future reviews in this population should be performed and directed to the DUR Board for further evaluation.

After reviewing the data from the utilization review, the DUR Board was provided the following:

**Drug Utilization Review: Long Acting Injectable Antipsychotic utilization as related to the SUPPORT Act**

**Next Steps:**

Continue to monitor the use of oral and injectable antipsychotics across the entire Medicaid population.

Note: This was not a voting agenda item

**G. Final Comments and Adjournment**

Approx. Webcast Time 3:29:12

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

Contact for meeting and meeting summary questions: [DUR@health.ny.gov](mailto:DUR@health.ny.gov) or 518-486-3209

**Meeting adjourned at 2:15 PM**

**H. 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 the PDP therapeutic class reviewed (and preferred or non-preferred status modifications) are estimated at \$532K. The savings would be achieved through utilization changes and the receipt of supplemental rebates from pharmaceutical manufacturers.