

**New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for May 12, 2022**

The Medicaid DUR Board met on Thursday, May 12, 2022, from 9:00am to 4:00pm.

The meeting was available for public viewing by way of Meeting Room 2, Empire State Plaza, Concourse Level, Albany, New York, and a live webcast.

The archived webcast of the meeting proceedings is available on the Department of Health website at: <http://www.health.ny.gov/events/webcasts/>

Meeting presentation slides can be found here:
https://www.health.ny.gov/health_care/medicaid/program/dur/meetings/2022/05/attachment.pdf

A. Welcome and Introduction

Approximate Webcast Time 00:00:14

Department of Health (DOH)

Douglas Fish, MD - Medicaid Medical Director and DUR Board Chairperson
Kimberly Leonard RPh - Medicaid Pharmacy Director
Anthony Merola, RPh, MBA
Monica Toohey, RPh
Kimberly Laurenzo, PharmD
Jacqueline Nahlik

DUR Board Members (DUR Board Membership)

Lisa Anzisi, PharmD	Jadwiga Najib, PharmD
Joseph Chiarella, MD	John Powell
Donna Chiefari, PharmD	Casey Quinn, PhD
James Hopsicker, RPh, MBA	Gloria Rodriguez, MD
Renante Ignacio, MD	Tara Thomas, RPh, MBA
Brock Lape	Jamie Wooldridge, MD
Peter Lopatka, FSA	

Magellan Medicaid Administration (MMA)

Mina Kwon, PharmD
Eileen Zimmer, PharmD

University at Buffalo (UB) School of Pharmacy and Pharmaceutical Sciences

Linda Catanzaro, PharmD
Irene Reilly, PharmD
Barbara Rogler, PharmD, MS

B. Public Comment Period

Approximate Webcast Time 00:04:06

The following speakers provided public comment to the DUR Board:

1.	Nirali Patel	Abbvie	Antimigraine Agents-Other
2.	Nirali Patel	Abbvie	Antimigraine Agents-Other
3.	Elizabeth Lubelczyk	Eli Lilly	Antimigraine Agents-Other
4.	Daniel Flores	Amgen	Antimigraine Agents-Other
5.	Charles Argoff	Albany Medical Center	Antimigraine Agents-Other
6.	Nicolas Saikali	Dent Neurologic Institute	Antimigraine Agents-Other
7.	Paul Isikwe	Teva	Antimigraine Agents-Other
8.	Paul Isikwe	Teva	Movement Disorder Agents
9.	John Deason	Neurocrine Biosciences	Movement Disorder Agents
10.	Matthew Shapiro	NAMI-NYS	Movement Disorder Agents
11.	Elizabeth Lubelczyk	Eli Lilly	GLP-1 Agonists
12.	Corey O'Brien	NovoNordisk	GLP-1 Agonists
13.	Dana Canning	GSK	Anticholinergics/COPD Agents
14.	Nicole Trask	Janssen	esketamine (Spravato)

C. Drug Utilization Review (DUR)

Approximate Webcast Time 00:46.59

The DUR Board reviewed information regarding esketamine nasal spray (Spravato), as summarized below, and recommended clinical criteria to ensure appropriate drug utilization.

Presenter: Dr. Irene Reilly

Esketamine is an N-methyl-D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults and depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior. Because of the risk of abuse and misuse, esketamine nasal spray is a Schedule III controlled substance.

The information presented included limitation of use, dosage regimens, and the Risk Evaluation and Mitigation Strategy program. An overview of Major Depressive Disorder (MDD) and Treatment Resistant Depression (TRD) was also provided, inclusive of treatment guidelines and drug development trials.

Based on the information presented, UB School of Pharmacy and Pharmaceutical Sciences recommended that Spravato (esketamine) require prior authorization: (1) to confirm FDA-approved and compendia-supported uses; (2) to ensure providers attest that before initiating esketamine intranasal therapy, they obtained a baseline score on a clinical assessment tool (e.g., 17-item Hamilton Rating Scale for Depression (HAM-D17), 16-item Quick Inventory of Depressive Symptomatology (QIDS-C16), 10-item Montgomery-Asberg Depression Rating Scale (MADRS)); (3) to require the use of at least 2 oral antidepressants, for an adequate duration and at an adequate dose with or without adjunctive therapy, before initiating therapy; (4) to require concomitant use with an oral antidepressant; (5) to ensure prescription renewal criteria that includes utilization of same clinical assessment tool that was used at baseline, whereas the provider attests that the therapy has resulted in an

improvement in depressive symptoms for the patient; and (6) to ensure providers are monitoring for signs of potential drug abuse or misuse.

DOH noted that prospective claims system editing (ProDUR) is currently used to confirm:

- FDA-approved or compendia-supported uses:
 - Treatment Resistant Depression (TRD) in adults.
 - Depressive symptoms in adults with Major Depressive Disorder (MDD) with acute suicidal ideation or behavior.
- Concurrent use with an oral antidepressant.

The DUR Board discussed the recommendation to require the use of at least 2 oral antidepressants before initiating Spravato (esketamine) nasal spray in terms of diagnosis (MDD and TRD). It was suggested that step therapy with 2 oral antidepressants may only need to apply for a diagnosis of TRD because in terms of MDD, step therapy may lead to a delay in treatment. The DUR Board made a modification to the recommendation as indicated below in recommendation #2.

The DOH recommendations to the DUR Board, including any DUR Board modifications, are as follows:

The DOH recommendations to the DUR Board, including any DUR Board modifications	Commissioner's Final Determination
<p>Recommendation #1:</p> <p>Before initiating esketamine nasal spray (Spravato), prescribers must attest that they have obtained a baseline score using a validated clinical assessment tool for depression (e.g., HAMD17, QIDS-C16C, MADRS).</p> <p>Vote: In Favor 13 / Against 0 / Abstentions 0</p> <p>-----</p> <p>Recommendation #2:</p> <p>Trial of at least two oral antidepressants prior to esketamine nasal spray (Spravato).</p> <p>Recommendation modified by DUR Board:</p> <p>Trial of at least two oral antidepressants prior to esketamine nasal spray (Spravato) when used for Treatment Resistant Depression.</p> <p>Vote: In Favor 13 / Against 0 / Abstentions 0</p> <p>-----</p> <p>Recommendation #3:</p> <p>After the initiation of esketamine nasal spray (Spravato) therapy, every six months prescribers must attest that esketamine nasal spray (Spravato) has resulted in an improvement of depressive symptoms (from baseline) using the same baseline clinical assessment tool for depression (e.g., HAMD17, QIDS-C16C, MADRS).</p> <p>Vote: In Favor 13 / Against 0 / Abstentions 0</p>	<p>Approved as Recommended</p>

D. Preferred Drug Program (PDP) Clinical Review

Approximate Webcast Time 01:40:00

The DUR Board reviewed new clinical information (new since the previous review of the therapeutic class) for three therapeutic classes as summarized below and then considered financial information for all ten therapeutic classes while in executive session.

Presenter: Mina Kwon

1. Antimigraine Agents – Other

New Drug Entity: Qulipta (atogepant)

Calcitonin gene-related peptide antagonist indicated for the preventive treatment of episodic migraine in adults.

New Indication & Key Label Revisions: Nurtec ODT (rimegepant)

FDA approved for preventative treatment of episodic migraine in adults; previously approved only for acute treatment of migraine with or without aura in adults.

2. Acne Agents – Topical

New Drug Entity: Winlevi (clascoterone)

Androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

Clinical Comparative Studies (within class):

- None available

3. Growth Hormones

New Drug Entity: Skytrofa (lonapegsomatropin-tcgd)

Human growth hormone indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone.

E. Executive Session (PDP Financial Reviews)

Approximate Webcast Time 01:54:42

The DUR Board recessed to executive session at 11:30am to review confidential financial information associated with the Preferred Drug Program. The following therapeutic classes were reviewed in executive session:

1. Cholesterol Absorption Inhibitors
2. Antimigraine Agents – Other
3. Movement Disorder Agents
4. Acne Agents - Topical

- 5. Antifungals - Topical
- 6. Dipeptidyl Peptidase-4 (DPP-4) Inhibitors
- 7. Glucagon-like Peptide-1 (GLP-1) Agonists
- 8. Growth Hormones
- 9. Antihyperuricemics
- 10. Anticholinergics/COPD Agents

The DUR Board reconvened to the public session at 1:00pm. No official action was taken during executive session.

F. DUR Board PDP Recommendations

Approximate Webcast Time 01:56:20

The DOH recommendations to the DUR Board, including any DUR Board modifications	Commissioner's Final Determination
<p>1. Cholesterol Absorption Inhibitors</p> <p>Preferred: cholestyramine, cholestyramine light, Colestid (tablet), colestipol (tablet), ezetimibe</p> <p>Non- Preferred: colesevelam, Colestid (granules, packet), colestipol (granules, packet), Questran, Questran Light, Welchol, Zetia</p> <p>Vote: In Favor 13 / Against 0 / Abstentions 0</p>	<p>Approved as Recommended</p>
<p>2. Antimigraine Agents – Other</p> <p>Preferred: Ajoovy, Emgality, Nurteq ODT</p> <p>Non-Preferred: Aimovig, Emgality 100mg syringe, Qulipta, Reyvow, Ubrelvy</p> <p>Vote: In Favor 13 / Against 0 / Abstentions 0</p>	<p>Approved as Recommended</p>
<p>3. Movement Disorder Agents</p> <p>Preferred: Austedo, Ingrezza, tetrabenazine</p> <p>Non-Preferred: Xenazine</p> <p>Vote: In Favor 13 / Against 0 / Abstentions 0</p>	<p>Approved as Recommended</p>

<p>4. Acne Agents- Topical</p> <p>Preferred: adapalene/benzoyl peroxide (generic Epiduo), adapalene cream, Differin OTC (1% gel), Retin-A cream, tazarotene cream, tretinoin gel (generic Avita, Retin-A)</p> <p>Non-Preferred: adapalene (gel, gel pump), adapalene/benzoyl peroxide (generic Epiduo Forte), Aklief, Altreno, Amzeeq, Arazlo, Atralin, Avita, clindamycin/tretinoin, dapsone, Differin (Rx gel, soln, lotion, cream), Epiduo Forte, Fabior, Retin-A gel, Retin-A micro, tazarotene foam (generic Fabior), tretinoin cream, gel (generic Atralin), tretinoin micro, Twyneo, Winlevi, Ziana</p> <p>Vote: In Favor 13 / Against 0 / Abstentions 0</p>	<p>Approved as Recommended</p>
<p>5. Anti-Fungals – Topical</p> <p>Preferred: ciclopirox (cream, suspension), clotrimazole OTC, clotrimazole/betamethasone (cream), ketoconazole (cream, shampoo), miconazole OTC, nystatin (cream, ointment, powder), terbinafine OTC, tolnaftate OTC</p> <p>Non-Preferred: Alevazol OTC, Ciclodan (cream), ciclopirox (gel, shampoo), clotrimazole/betameth (lotion), clotrimazole Rx, econazole, Ertaczo, Exelderm, Extina, ketoconazole (foam), Loprox shampoo, luliconazole, Luzu, Mentax, miconazole/zinc/petrolatum (gen Vusion), naftifine, Naftin, nystatin/triamcinolone, oxiconazole, Oxistat, sulconazole (generic Exelderm), Vusion</p> <p>Vote: In Favor 13 / Against 0 / Abstentions 0</p>	<p>Approved as Recommended</p>
<p>6. Dipeptidyl Peptidase-4 (DPP-4) Inhibitors</p> <p>Preferred: Glyxambi, Janumet, Janumet XR, Januvia, Jentadueto, Kazano, Nesina, Tradjenta</p> <p>Non-Preferred: alogliptan, alogliptan/metformin, alogliptan/pioglitazone, Jentadueto XR, Kombiglyze XR, Onglyza, Oseni, Qtern, Steglujan</p> <p>Vote: In Favor 13 / Against 0 / Abstentions 0</p>	<p>Approved as Recommended</p>
<p>7. Glucagon-like Peptide-1 (GLP-1) Agonists</p> <p>Preferred: Byetta, Ozempic, Trulicity, Victoza</p> <p>Non-Preferred: Adlyxin, Bydureon Bcise, Rybelsus, Soliqua, Xultophy</p> <p>Vote: In Favor 13 / Against 0 / Abstentions 0</p>	<p>Approved as Recommended</p>

<p>8. Growth Hormones</p> <p>Preferred: Genotropin, Norditropin</p> <p>Non-Preferred: Humatrope, Nutropin AQ, Omnitrope, Saizen, Skytrofa, Zomacton, Zorbtive</p> <p>Vote: In Favor 13 / Against 0 / Abstentions 0</p>	<p>Approved as Recommended</p>
<p>9. Antihyperuricemics</p> <p>Preferred: allopurinol, colchicine (tablet), febuxostat, probenecid, probenecid/colchicine</p> <p>Non-Preferred: colchicine (capsule), Colcrys, Gloperba, Mitigare, Uloric, Zylprim</p> <p>Vote: In Favor 13 / Against 0 / Abstentions 0</p>	<p>Approved as Recommended</p>
<p>10. Anticholinergics/COPD Agents</p> <p>Preferred: Anoro Ellipta, Atrovent HFA, Bevespi Aerosphere, Combivent Respimat, ipratropium, ipratropium/albuterol, Spiriva, Spiriva Respimat, Stiolto Respimat</p> <p>Non-Preferred: Breztri Aerosphere, Daliresp, Duaklir Pressair, Incruse Ellipta, Lonhala Magnair, Trelegy Ellipta, Tudorza Pressair, Yupelri</p> <p>Vote: In Favor 13 / Against 0 / Abstentions 0</p>	<p>Approved as Recommended</p>

G. Pharmacy Program Updates

Approximate Webcast Time 02:09:00

The DUR Board was presented information regarding asthma guidelines and the use of inhaled corticosteroids / long-acting beta agonist combinations for maintenance and reliever therapy as summarized below.

Presenter: Dr. Linda Catanzaro

The 2020 National Asthma Education and Prevention Program (NAEPP) guideline updates include a strong recommendation for use of ICS-formoterol as single maintenance and reliever therapy (SMART) in patients ≥4 years of age with moderate to severe asthma. The Expert Panel notes that strong recommendations “can be adapted as policy or performance measures in most situations”.

Though FDA labeling for ICS-formoterol products states they are not indicated for treatment of acute bronchospasm, the guideline recommendations for SMART are included with FDA uses in official compendia.

Overall Fee-for-Service (FFS) and Managed Care (MC) utilization of ICS-LABA (both members and claims) has increased from 2019 through 2021.

The guideline recommendation for use of ICS-formoterol as SMART in patients ≥4 years of age presents the following considerations for NYS Medicaid FFS members:

- Symbicort and Dulera are both preferred drugs on the FFS Preferred Drug List. Prior authorization is required for all new LABA prescriptions, including Dulera and Symbicort, for members **under** FDA or compendia-supported age limits.
- Dulera is FDA-approved for treatment of asthma in patients aged ≥5 years. Symbicort is FDA-approved for treatment of asthma in patients aged ≥6 years. Both drugs are compendia-supported for use as SMART in ages ≥4 years. DOH will be updating the age edit on Dulera and Symbicort to ≥ 4 years.
- Frequency, Quantity, Duration (F/Q/D) limits for both products are currently one inhaler every 30 days. Higher quantities and/or more frequent refills may be needed for SMART.

The current quantity limit for mometasone/formoterol (Dulera) and budesonide/formoterol (Symbicort) is one inhaler every 30 days. The DUR Board discussed the current quantity limit including suggestions on how the quantity limit might be modified to allow for additional inhaler(s) to accommodate SMART. As a result of the discussion, the DUR Board recommended a change to the current quantity limit as provided below.

The DUR Board made the following recommendations to DOH for formoterol/budesonide (Symbicort) and formoterol/mometasone (Dulera):

The DUR Board recommendation	Commissioner's Final Determination
<p>The quantity limit for mometasone/formoterol (Dulera) and budesonide/formoterol (Symbicort) be changed to allow for the dispensing of up to two additional inhalers over a 180 day period.</p> <p>Vote: In Favor 14 / Against 0 / Abstentions 0</p>	<p>Approved as Recommended</p>

H. Final Comments and Adjournment

Approximate Webcast Time 03:12:00

Douglas Fish
 Kimberly Leonard
 Anthony Merola

Meeting adjourned at 2:30pm

Contact information: DUR@health.ny.gov or 518-486-3209
[Drug Utilization Review \(DUR\) \(ny.gov\)](http://www.health.ny.gov/programs/dur/)

I. Commissioner Final Determination

The impact of the final determinations, associated with the PDP, is as follows:

State Public Health Population:

- Minimal effect on Medicaid members, as a large majority of beneficiaries currently utilize preferred products. Non-preferred products remain available with prior authorization. Prior authorization will help ensure the utilization of medication is clinically appropriate and not likely to result in adverse medical outcomes.

Program Providers:

- No impact on prescribers when utilizing preferred products. Prescribers, or their agents, may need to initiate the prior authorization process when ordering non-preferred products or for other medications that may have clinical criteria in place.

State Health Program:

- Annual gross savings associated with the PDP therapeutic class reviewed, and associated preferred or non-preferred status modifications, are estimated at \$1.4 million. The savings would be achieved through utilization changes and the receipt of supplemental rebates from pharmaceutical manufacturers.