New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for July 14, 2022

The Medicaid DUR Board met on Thursday, July 14th, 2022, from 9:00am to 4:30pm.

The meeting was offered for public viewing by way of:
- Meeting Room 2, Empire State Plaza, Concourse Level, Albany, NY.
- Meeting Room 443, University at Buffalo, School of Pharmacy, Buffalo, NY.
- Live webcast.

Webcast

Meeting Documents

Meeting Transcript

A. Welcome and Introductions

Department of Health (DOH)
Douglas Fish – DUR Board Chairperson
Kimberly Laurenzo
Kimberly Leonard – Medicaid Pharmacy Director
Anthony Merola
Monica Toohey

DUR Board Members (DUR Board Membership)
Asa Radix
Joseph Chiarella
Donna Chiefari
Marla Eglowstein
Renante Ignacio
Brock Lape
Jill Lavigne
Peter Lopatka
Jadwiga Najib
John Powell
Casey Quinn
Tara Thomas
Deborah Wittman

Magellan Medicaid Administration (MMA)
Mina Kwon
Eileen Zimmer
B. Public Comment Period

The following speakers provided public comment to the DUR Board:

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<tr>
<th>Name</th>
<th>Organization</th>
<th>Agenda Item</th>
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</thead>
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<tr>
<td>Timothy Birner</td>
<td>Alkermes</td>
<td>Antipsychotics - Injectable</td>
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<tr>
<td>Timothy Birner</td>
<td>Alkermes</td>
<td>Antipsychotics - 2nd Generation</td>
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<tr>
<td>Kimberly Blair</td>
<td>NAMI-NYC</td>
<td>Antipsychotics - 2nd Generation</td>
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<tr>
<td>Ameen Saleem</td>
<td>Intra-Cellular Thera.</td>
<td>Antipsychotics - 2nd Generation</td>
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<td>Arden Arslanyan</td>
<td>Otsuka</td>
<td>Antipsychotics - 2nd Generation</td>
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<tr>
<td>Steven Burch</td>
<td>Sunovion</td>
<td>Antipsychotics - 2nd Generation</td>
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<td>Nirali Patel</td>
<td>Abbvie</td>
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<td>Nirali Patel</td>
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<td>Immunomodulators - Systemic</td>
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<td>Abbvie</td>
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<tr>
<td>Daniel Shan</td>
<td>UBC</td>
<td>Immunomodulators - Systemic</td>
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<tr>
<td>Richard Kraft</td>
<td>AstraZeneca</td>
<td>Immunomodulators - Systemic</td>
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<tr>
<td>Ted Riley</td>
<td>GSK</td>
<td>Immunomodulators - Systemic</td>
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<tr>
<td>Aaron Waltzer</td>
<td>Pfizer</td>
<td>Immunomodulators - Systemic</td>
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<tr>
<td>Yulia Rozovskiy</td>
<td>Pfizer</td>
<td>Immunomodulators - Systemic</td>
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<tr>
<td>Daniel Flores</td>
<td>Amgen</td>
<td>Immunomodulators - Systemic</td>
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<td>Immunomodulators – Systemic</td>
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<tr>
<td>Lane Anson</td>
<td>Sanofi</td>
<td>Immunomodulators – Systemic</td>
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<tr>
<td>Elizabeth Lubelczyk</td>
<td>Eli Lilly</td>
<td>Immunomodulators - Systemic</td>
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<tr>
<td>Elizabeth Lubelczyk</td>
<td>Eli Lilly</td>
<td>Glucagon Agents</td>
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C. Pharmacy Program Update(s)

The DUR Board was presented information regarding the management of physician/practitioner administered drugs (PADs).

D. Preferred Drug Program (PDP) Clinical Review

The DUR Board reviewed new clinical information (new since the previous review of the therapeutic class) and then considered financial information during executive session.

E. Executive Session - PDP Financial Reviews

The DUR Board recessed to executive session at 11:50am to review confidential financial information associated with the Preferred Drug Program.
The DUR Board reconvened to the public session at 1:00pm. No official action was taken during executive session.

F. DUR Board PDP Recommendations

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

<table>
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<th>Recommendations</th>
<th>Commissioner’s Final Determination</th>
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<tr>
<td><strong>1. Antipsychotics - Injectable</strong></td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td>Preferred: Abilify Maintena, Aristada, Aristada Initio, fluphenazine decanoate, Haldol decanoate, haloperidol decanoate, Invega Hafyera, Invega Sustenna, Invega Trinza, Perseris, Risperdal Consta, Zyprexa Relprevv</td>
<td></td>
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<tr>
<td>Non- Preferred: None</td>
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<tr>
<td>Vote: In Favor 14 / Against 0 / Abstentions 0</td>
<td></td>
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</tbody>
</table>

| **2. Antipsychotics – Second Generation CC, ST** | Approved as Recommended |
| Preferred: aripiprazole (tablet), asenapine (generic Saphris), clozapine, Latuda, olanzapine (tablet), quetiapine, quetiapine ER, risperidone, ziprasidone (capsule) | |
| Non-Preferred: Abilify (tablet), Abilify MyCite, aripiprazole (solution), aripiprazole ODT, Caplyta, clozapine ODT, Clozaril, Fanapt, Geodon, Invega, Lybalvi, Nuplazid, olanzapine ODT, paliperidone ER, Rexulti, Risperdal, Saphris, Secuado, Seroquel, Seroquel XR, Versacloz, Vraylar, Zyprexa, Zyprexa Zydis | |
| CC = Clinical Criteria  
ST = Step Therapy | |
| Vote: In Favor 14 / Against 0 / Abstentions 0 | |
### 3. Other Agents for Attention Deficit Hyperactivity Disorder (CC)

**Preferred:** atomoxetine, clonidine ER, guanfacine ER  
**Non-Preferred:** Intuniv, Qelbree, Strattera

CC = Clinical Criteria  
Vote: In Favor 14 / Against 0 / Abstentions 0

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### 4. Immunomodulators – Systemic (CC, ST)

**Preferred:** Cosentyx, Dupixent, Enbrel, Fasenra, Humira, Nucala, Xolair  
**Non-Preferred:** Actemra (SQ), Adbry, Cibinqo, Cimzia, Ilumya, Kevzara, Kineret, Olumiant, Oremia (SQ), Otezla, Rinvoq ER, Siliq, Simponi, Skyrizi, Stelara, Taltz, Tremfya, Xeljanz, Xeljanz XR

Indication Specific requirements for Atopic Dermatitis:  
- Trial with a topical prescription product for a duration of at least 3 months.  
- For Janus kinase (JAK) inhibitors: Trial of topical prescription product and systemic product for a combined duration of at least 6 months.

CC = Clinical Criteria  
ST = Step Therapy  
Vote: In Favor 14 / Against 0 / Abstentions 0

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### 5. Glucagon Agents

**Preferred:** glucagon (injection), glucagon hcl emergency kit, Zegalogue  
**Non-Preferred:** Baqsimi, glucagon emergency kit, Gvoke

Vote: In Favor 14 / Against 0 / Abstentions 0

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For reference: [New York State Medicaid Fee-for-Service Preferred Drug List](#)

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**G. Drug Utilization Review (DUR)**

The DUR Board reviewed the drugs/drug classes listed below and recommend clinical criteria to ensure appropriate drug utilization.
The DOH recommendations to the DUR Board, including any DUR Board modifications:

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Commissioner’s Final Determinations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Aducanumab (Aduhelm)</strong></td>
<td>Approved as Recommended</td>
</tr>
</tbody>
</table>
| Before initiating aducanumab (Aduhelm), prescribers must attest that the patient has been diagnosed with mild cognitive impairment due to Alzheimer’s Disease or mild Alzheimer’s dementia by meeting one of the following:  
  • Clinical Dementia Rating (CDR)-Global score of 0.5 to 1  
  • Mini-Mental Status Exam (MMSE) score between 24 and 30  
  • Montreal Cognitive Assessment (MoCA) score of at least 18 | Vote: In Favor 13 / Against 0 / Abstentions 0 |
| Before initiating aducanumab (Aduhelm), prescribers must attest that the patient has undergone the following pre-treatment testing:  
  • Genetic testing to assess apolipoprotein Eε4 carrier status AND  
  • Positron emission tomography (PET) scan or cerebrospinal fluid (CSF) analysis to confirm the presence of amyloid beta deposits |  |
| The DUR Board modified the DOH recommendation as follows:  
Before initiating aducanumab (Aduhelm), prescribers must provide the medical records for the following pre-treatment testing:  
  • Genetic testing to assess apolipoprotein Eε4 carrier status AND  
  • Positron emission tomography (PET) scan or cerebrospinal fluid (CSF) analysis to confirm the presence of amyloid beta deposits | Vote: In Favor 13 / Against 0 / Abstentions 0 |
| Before initiating aducanumab (Aduhelm), prescribers must attest that the patient does not have evidence of any medical or neurological condition other than Alzheimer’s Disease that could be contributing to the patient’s cognitive impairment. | Vote: In Favor 13 / Against 0 / Abstentions 0 |
Before initiating aducanumab (Aduhelm), prescribers must attest that the patient does not have a history of a clotting disorder and is not taking any form of antiplatelet or anticoagulant medications other than aspirin ≤325 mg/day.

Vote: In Favor 13 / Against 0 / Abstentions 0

The DUR Board motioned to include an additional recommendation related to continuation of therapy as follows:

For continuation of therapy, providers must attest that the patient’s score remained stable or improved, utilizing the same baseline assessment tool as outlined in the first recommendation:

- Clinical Dementia Rating (CDR)-Global score of 0.5 to 1
- Mini-Mental Status Exam (MMSE) score between 24 and 30
- Montreal Cognitive Assessment (MoCA) score of at least 18

Vote: In Favor 13 / Against 0 / Abstentions 0

2. **Botulinum Toxins onabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport), rimabotulinumtoxinB (Myobloc), inobotulinumtoxinA (Xeomin)**

Given the indications below, a trial of the product(s) listed in the step therapy column prior to use of botulinum toxin:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic sialorrhea*</td>
<td>Glycopyrrolate</td>
</tr>
<tr>
<td>Headache prevention in patients with chronic migraine</td>
<td>Two oral agents FDA-approved or compendia-supported for prevention of migraine</td>
</tr>
<tr>
<td>Overactive bladder</td>
<td>Antimuscarinic agent or beta-3-adrenoceptor agonist</td>
</tr>
<tr>
<td>Neurogenic detrusor overactivity**</td>
<td>Antimuscarinic agent</td>
</tr>
<tr>
<td>Urinary incontinence due to detrusor overactivity</td>
<td>Antimuscarinic agent or beta-3-adrenoceptor agonist</td>
</tr>
</tbody>
</table>

*excludes patients with Parkinson’s and other neurodegenerative diseases
**excludes patients with multiple sclerosis or spinal cord injury

Vote: In Favor 12 / Against 0 / Abstentions 0
3. Infliximab (Remicade), infliximab-abda (Renflexis), infliximab-axxq (Avsola), infliximab-dyyb (Inflectra)

   Trial of a disease-modifying anti-rheumatic drug (DMARD) or tumor necrosis factor inhibitor (TNFi) FDA approved for self-administration prior to initiation of infliximab.

   Vote: In Favor 12 / Against 0 / Abstentions 0

   Approved as Recommended

4. Vedolizumab (Entyvio)

   Trial of a disease-modifying anti-rheumatic drug (DMARD) or tumor necrosis factor inhibitor (TNFi) prior to initiation of vedolizumab.

   Vote: In Favor 12 / Against 0 / Abstentions 0

   Approved as Recommended

H. Final Comments and Adjournment

   Meeting adjourned at 4:00pm

   Contact information: DUR@health.ny.gov or 518-486-3209
   Drug Utilization Review (DUR) (ny.gov)

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 classes reviewed, and associated preferred or non-preferred status modifications, are estimated at $123,500. The savings would be achieved through utilization changes and the receipt of supplemental rebates from pharmaceutical manufacturers.