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

University at Buffalo – School of Pharmacy and Pharmaceutical Sciences
Holly Coe
Tzu-Yin Kuo
Barbara Rogler

B. Public Comment Period

The following speakers provided public comment to the DUR Board:

Name	Organization	Agenda Item
1. Timothy Birner	Alkermes	Antipsychotics - Injectable
2. Timothy Birner	Alkermes	Antipsychotics - 2nd Generation
3. Kimberly Blair	NAMI-NYC	Antipsychotics - 2nd Generation
4. Ameen Saleem	Intra-Cellular Thera.	Antipsychotics - 2nd Generation
5. Arden Arslanyan	Otsuka	Antipsychotics - 2nd Generation
6. Steven Burch	Sunovion	Antipsychotics - 2nd Generation
7. Nirali Patel	Abbvie	Antipsychotics - 2nd Generation
8. Nirali Patel	Abbvie	Immunomodulators - Systemic
9. Nirali Patel	Abbvie	Immunomodulators - Systemic
10. Daniel Shan	UBC	Immunomodulators - Systemic
11. Richard Kraft	AstraZeneca	Immunomodulators - Systemic
12. Ted Riley	GSK	Immunomodulators - Systemic
13. Aaron Waltzer	Pfizer	Immunomodulators - Systemic
14. Yulia Rozovskiy	Pfizer	Immunomodulators - Systemic
15. Daniel Flores	Amgen	Immunomodulators - Systemic
16. Daniel Flores	Amgen	Immunomodulators – Systemic
17. Lane Anson	Sanofi	Immunomodulators – Systemic
18. Elizabeth Lubelczyk	Eli Lilly	Immunomodulators - Systemic
19. Elizabeth Lubelczyk	Eli Lilly	Glucagon Agents

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

NYS Medicaid Pharmacy Programs | Preferred Drug Program (fhsc.com)

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:

Recommendations	Commissioner's Final Determination
1. Antipsychotics - Injectable **Preferred**: Abilify Maintena, Aristada, Aristada Initio, fluphenazine decanoate, Haldol decanoate, haloperidol decanoate, Invega Hafyera, Invega Sustenna, Invega Trinza, Perseris, Risperdal Consta, Zyprexa Relprevv **Non- Preferred**: None Vote: In Favor 14 / Against 0 / Abstentions 0	Approved as Recommended
2. Antipsychotics – Second Generation [CC, ST] **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	Approved as Recommended

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	Approved as Recommended
4. Immunomodulators – Systemic [CC, ST] **Preferred:** Cosentyx, Dupixent, Enbrel, Fasenra, Humira, Nucala, Xolair **Non-Preferred:** Actemra (SQ), Adbry, Cibinqo, Cimzia, Ilumya, Kevzara, Kineret, Olumiant, Orencia (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	Approved as Recommended
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	Approved as Recommended

For reference**:** New York State Medicaid Fee-for-Service Preferred Drug List

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:

Recommendations	Commissioner's Final Determinations
1. Aduncanumab (Aduhelm) 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 E ε4 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	Approved as Recommended

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:

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

*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

Approved as Recommended

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.