New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for July 15, 2021

The Medicaid DUR Board met on Thursday, July 15th, 2021 from 9:00am to 1:00pm.

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

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

A. Welcome and Introduction

Approximate Webcast Time 00:00:09

Department of Health

Douglas Fish, MD – DUR Board Chairperson
Amir Bassiri, Deputy Medicaid Director
Robert Correia, PharmD
Kimberly Laurenzo, PharmD
Anthony Merola, RPh, MBA
Jacqueline Nahlik, HPA
Robert Sheehan, RPh
Monica Toohey, RPh

DUR Board Members

Lisa Anzisi, PharmD
Donna Chiefari, PharmD
Marla Eglowstein, MD
James Hopsicker, RPh, MBA
Renante Ignacio, MD
Jacqueline Jacobi, PharmD
Jill Lavigne, PhD, MS, MPH
Peter Lopatka, FSA
Jadwiga Najib, PharmD
Michael Pasquarella, PharmD
John Powell
Casey Quinn, PhD
Asa Radix, MD
Tara Thomas, RPh, MBA, MPA
Jamie Wooldridge, MD

Magellan Rx Management

Eileen Zimmer, PharmD

SUNY – University at Buffalo

Holly Coe, PharmD

B. Public Comment Period
Approximate Webcast Time 00:05:55

The following speakers provided public comment to the DUR Board:

1	Vince Florio	UCB	Anticonvulsants - Other
2	Kendra Davies, PharmD	Greenwich Bio	Anticonvulsant - Other
3	Matthew Clark, Sr.	Zogenix	Anticonvulsant - Other
4	Joseph Cirrinicione, PharmD	Otsuka Pharm	Antipsychotic - Injectables
5	Kenny Ng, PharmD	Indivior	Antipsychotic - Injectables
6	Matthew Shapiro	NAMI-NYS	Antipsychotics - Injectables
7	Beth D'Ambrosio, PharmD	Novartis	Multiple Sclerosis Agents
8	John Donovan	BMS	Multiple Sclerosis Agents

C. Preferred Drug Program (PDP) Clinical Review
Approximate Webcast Time 00:32:07

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

1. Anticonvulsants – Other

New products:
- Fintepla (fenfluramine) oral solution.
- Xcopri (cenobamate) oral tablets.

New indications:
- Spritam (levetiracetam) oral suspension – Treatment of partial-onset seizures (POS) in patients ≥ 4 years old weighing > 20 kg.
- Vimpat (lacosamide) - Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients ≥ 4 years of age.

FDA safety communications:
- Lamictal - Warns of a potential increased risk of arrhythmias in patients with heart disease as a result of reports of abnormal electrocardiograms (ECGs).

Key label revisions:
- Sympazan (clobazam) - Addition of cannabidiol drug interaction; cannabidiol can increase the risk for adverse effects.
- Qudexy XR, Trokendi XR (topiramate) - Addition of serious skin reactions to the Warnings and Precautions section to be consistent with Topamax.
- Spritam (levetiracetam) - Addition of a new Dosing and Administration subsection on discontinuation.

The recommendation for this drug class would be to have as much representation as practical in consideration of suspected mechanism of action and coverage of different FDA

indications, inclusive of special populations such as pediatrics, and with particular consideration of initial therapy for seizure disorders.

2. Multiple Sclerosis Agents

New products
- Ponvory (ponesimod).

New indications
- Zeposia (ozanimod) -Treatment of moderately to severely active ulcerative colitis (UC) in adults.

New formulation
- Plegridy (pegylated interferon beta-1a) – Intramuscular (IM) route of administration with corresponding prefilled syringe now available.

Label revisions
- *Warnings and precautions* - Mayzent (siponimod), risk of cutaneous malignancies.
- *Adverse drug reactions* - Tecfidera, Vumerity (dimethyl fumarate/diroximel fumarate), potential for rhinorrhea. Extavia, Betaseron (Interferon beta 1-b), potential for hemolytic anemia.

Updated Clinical Guidelines:
- American Academy of Neurology

  Choice of a disease modifying treatment (DMT) is based on upon safety, route of administration, efficacy, adverse events, tolerability, cost, and patient preferences (Level A recommendation).

  Patients with relapsing forms of MS (with recent clinical relapse or MRI activity) should be offered DMTs (Level B recommendation).

  Treatment initiation: current evidence supports higher efficacy in reduction of relapses and MRI lesion activity for fingolimod (Gilenya®) versus other approved self-injectable agents (e.g., interferon-β therapy) in patients with high disease activity (Level B recommendation).

- European Committee of Treatment and Research in Multiple Sclerosis/ European Academy of Neurology

  Early treatment with DMTs should be offered to patients with active relapsing-remitting Multiple Sclerosis (RRMS) with clinical relapses and/or MRI activity.

  Treatment for patients with active RRMS should be based on patient factors, including specific patient characteristics and comorbidities, disease severity/activity, safety profile of the drug, and accessibility to treatment (consensus statement).

For patients with active RRMS, consider treatment with an interferon β-1a, interferon β-1b, peginterferon β-1a, glatiramer acetate, teriflunomide, dimethyl fumarate, cladribine, or fingolimod (consensus statement).

In active secondary progressive MS, consider treatment with an interferon β-1a or 1b.

Recommendation to remove the step therapy requirements currently associated with the Multiple Sclerosis products on the Preferred Drug List.

Comparative studies between the oral agents is lacking. Evidence that these agents are better overall for all patients is lacking and each may demonstrate benefit verses risks for different patients.

3. Other Agents for Attention Deficit Hyperactivity Disorder

New Product
- Qelbree (viloxazine).

Head to head evidence between the drugs in this class is lacking and therefore, overall superiority between them, cannot be determined at this time.

4. Anticholinergics – COPD Agents

New product
- Breztri Aerosphere (budesonide formoterol fumarate/glycopyrrolate).

New indication
- Trelegy Ellipta now indicated for the maintenance treatment of asthma in adults.

New Practice guidelines

- Gold 2021 Report (Global Initiative for COPD)

Triple Therapy (LABA/LAMA/ICS) section incorporates new findings on triple therapy and mortality.

Large randomized clinical trials provide new evidence of a reduction in mortality, in symptomatic COPD patients, with a history of frequent and/or severe exacerbations, who are using a fixed dose inhaled triple therapy compared to dual therapy (LABA/LAMA).

Different products may be more appropriate at different points of disease progression. Quality evidence to support clinical superiority for any specific product in this class cannot be determined at this time.

D. Executive Session (PDP Financial Reviews)

The DUR Board recessed to executive session at 10:30am and reconvened to the public session at 11:30am.

E. DUR Board PDP Recommendations

Approximate Webcast Time 01:08:18

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's Final Determination
1. Anticonvulsants - Other **Preferred**: clobazam (tablet), gabapentin (caps, tab, soln), lamotrigine (tab, chew), levetiracetam, levetiracetam ER, Lyrica (cap), pregabalin (cap), tiagabine, topiramate, zonisamide **Non- Preferred**: Banzel, Briviact, clobazam (susp), Diacomit, Epidiolex, felbamate, Felbatol, Fintepla, Fycompa, Gabitril, Keppra, Keppra XR, Lamictal (tab,chew,dosepak), Lamictal ODT (tab,dosepak), Lamictal XR (tab,dosepak), lamotrigine (dosepak), lamotrigine ER, lamotrigine ODT (dosepak), Lyrica (soln), Lyrica DR, Neurontin, Onfi, pregabalin (soln), pregabalin ER, Qudexy XR, rufinamide, Sabril, Spritam, Sympazan Film, Topamax, topiramate ER, Trokendi XR, vigabatrin, Vimpat, Xcopri Vote: 16 yes, 0 no, 0 abstentions	Approved as Recommended
2. Antipsychotics - Injectable **Preferred:** Ability Maintena, Aristada, Aristada Initio, fluphenazine decanoate, Haldol decanoate, haloperidol decanoate, Invega Sustenna, Invega Trinza, Perseris, Risperdal Consta, Zyprexa Relprevv **Non-Preferred:** None Vote: 16 yes, 0 no, 0 abstentions	Approved as Recommended
3. Multiple Sclerosis Agents **Preferred:** Avonex, Betaseron, Copaxone 20 mg/ml, Tecfidera **Non-Preferred**: Aubagio, Bafiertam, Copaxone 40 mg/ml, dimethyl fumarate DR, Extavia, Gilenya, glatiramer, Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Vumerity, Zeposia The current Step Therapy requirements to be removed: - Trial with a preferred injectable product (Gilenya and Tecfidera). - Trial with a preferred oral agent (Aubagio, Bafiertam, Mavenclad, Mayzent, Ponvory Vumerity and Zeposia). Vote: 15 yes, 0 no, 1 abstention	Approved as Recommended

4. Other Agents for Attention Deficit Hyperactivity Disorder (ADHD) **Preferred:** atomoxetine, guanfacine ER **Non-Preferred:** clonidine ER, Intuniv, Qelbree, Strattera Vote: 16 yes, 0 no, 0 abstentions	Approved as Recommended
5. Actinic Keratosis Agents **Preferred:** diclofenac 3% gel, fluorouracil solution, fluorouracil 5% crm (generic Efudex), fluorouracil 0.5% crm (generic Carac), imiquimod 5% crm (generic Aldara) **Non-Preferred:** Aldara, Carac, Efudex, imiquimod 3.75% crm, pump (generic Zyclara), Picato, Tolak, Zyclara Vote: 16 yes, 0 no, 0 abstentions	Approved as Recommended
6. Glucocorticoids - Oral **Preferred:** dexamethasone (tablet), Entocort EC, hydrocortisone, methylprednisolone (dosepak), prednisolone (solution), prednisone (tablet, dosepak) **Non-Preferred**: Alkindi Sprinkle, budesonide EC, budesonide ER, Cortef, cortisone, dexamethasone (elixir, soln), dexamethasone intensol, Emflaza, Hemady, Medrol (dosepak, tablet), methylprednisolone (4mg, 8mg,16mg, 32 mg), Millipred (tab, dosepak), Ortikos, prednisolone ODT, prednisone (intensol, soln), Rayos, TaperDex, Uceris Vote: 16 yes, 0 no, 0 abstentions	Approved as Recommended
7. Phosphate Binders/Regulators **Preferred:** calcium acetate, Renagel, sevelamer carbonate tab **Non-Preferred:** Auryxia, Fosrenol, lanthanum carbonate, Phoslyra, Renvela, sevelamer HCL (generic Renagel), sevelamer carbonate pwd (generic Renvela), Velphoro Vote: 16 yes, 0 no, 0 abstentions	Approved as Recommended

8. Anticholinergics/COPD Agents **Preferred:** Anoro Ellipta, Atrovent HFA, Bevespi Aerosphere, Combivent Respimat, ipratropium, ipratropium/albuterol, Spiriva, Stiolto Respimat, Tudorza Pressair **Non-Preferred**: Breztri Aerosphere, Daliresp, Duaklir Pressair, Incruse Ellipta, Lonhala Magnair, Seebri Neohaler, Spiriva Respimat, Trelegy Ellipta, Utibron Neohaler, Yupelri Vote: 16 yes, 0 no, 0 abstentions	Approved as Recommended

F. Final Comments and Adjournment

Approximate Webcast Time 01:29:15

Douglas Fish, MD
Amir Bassiri
Anthony Merola, RPh, MBA

Contact for meeting and meeting summary questions: DUR@health.ny.gov or 518-486-3209

Meeting adjourned at 12:00pm

G. Commissioner Final Determinations

The impact of the PDP final determinations is as follows:

State Public Health Population:
Minimal effect on Medicaid members, as a large majority of members 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 associated preferred or non-preferred status modifications, are estimated at $1.4M. The savings would be achieved through utilization changes and the receipt of supplemental rebates from pharmaceutical manufacturers.