



New York State Medicaid Drug Utilization Review (DUR) Board Meeting Summary for September 20, 2018

The Medicaid DUR Board met on Thursday September 20, 2018 from 9:00 am to 4:00 pm Meeting Rooms 3 and 4, Concourse, Empire State Plaza, Albany, New York.

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 Introductions

Department of Health

Robert Correia, PharmD
Douglas Fish, MD (Chairperson)
Anthony Merola, RPh, MBA

Robert Sheehan, RPh
Monica Toohey, RPh
Janet Zachary-Elkind, BA

DUR Board Members

Lisa Anzisi, PharmD
Nancy Balkon, PhD, NP
Donna Chiefari, PharmD
James Hopsicker, RPh, MBA
Renato Ignacio, MD
Jacqueline Jacobi, RPh
Peter Lopatka, FSA

Christopher Murphy, MD
Jadiwga Najib, Pharm D
Casey Quinn, PhD
Asa Radix, MD
Michelle Rainka, PharmD
Tara Thomas, RPh, MBA
Maria Vullo, JD, MPA

Magellan Medical Administration

Eileen Zimmer, Pharm D, MBA

SUNY – University at Buffalo

Holly Coe, PharmD

Barbara Rogler, PharmD, MS

B. Public Comment Period

Audio Cast time -0:06:15 to 0:38:42

The following speakers provided public comment to the DUR Board:

- 1. Melinda Given United Therapeutics Orenitram
2. William Seidel Tris Pharma Dynavel XR
3. Elizabeth Lubelczyk Eli Lilly and Co. Talz, Olumiant
4. Beth D'Ambrosio Novartis Pharm. Cosentyx
5. Hiren Kacchia Celgene Otezla
6. Tom Kortschinsky UCB Cimzia
7. Daniel Flores Amgen Global Scientific Enbrel
8. Jean C. McGrath Brodeur Pfizer Xeljanz
9. Daniel Shan Shire Pharm. Xiidra

10. Nick Nguyen	Sunovion Pharm.	Lonhala Magnair
11. Jalpa K. Patel, PharmD	AstraZeneca	Bevespi
12. Daniel Flores, PharmD, MSc	Amgen Global Scientific	Aimovig

C. Preferred Drug Program (PDP) Clinical and Financial Review

Audio Cast time -0:38:47 to 1:18:08

Eileen Zimmer, Pharm D, MBA
Robert Correia, Pharm D

Eight Therapeutic Classes of the Preferred Drug Program were reviewed with new clinical and/or financial information.

A new class entitled “Anti-inflammatories, Immunomodulators, Ophthalmics” was added to the Preferred Drug Program.

1. Fluoroquinolones – Oral
 - New product – Baxdela
 - FDA safety communication: Class Effect
2. Pulmonary Arterial Hypertension Agents – Oral
 - No new clinical information
3. Central Nervous System Agents – Stimulants
 - No new clinical information
4. Helicobacter Pylori Agents
 - No new clinical information
5. Immunomodulators – Systemic
 - New products – Kevzara (sarilumab), Olumiant (baricitinib), Tremfya (guselkumab), Benlysta (belimumab)
 - New Indications
 - New formulations/strengths
 - Key label revisions
 - Practice guideline updates
 - Evidence/guidelines indicate that TNF inhibitors generally seem to have better efficacy than non-TNF biologics, however products with anti-TNF activity have been associated with more and more serious adverse effects than non-TNF drugs.
 - There is a step edit already in place for this drug class consistent with guidelines for use of a DMARD first, prior to use of a biological
6. Anti-inflammatories/Immunomodulators – Ophthalmics
 - Drugs: Restasis, Restasis Multidose, Xiidra
 - Background of the disease state

- Indications
- Dosage and administration
- Additional prescribing information
- Proposed mechanisms of action
- There is a “step edit” in place for this drug class for use of an ocular lubricant such as artificial tears prior to use of either of these drugs.

7. Prostaglandin Agonists – Ophthalmics

- New product – Vyzulta (latanoprostene bunod)
- Marginal differences have been claimed for each drug or product in terms of efficacy or adverse effects with none demonstrating an overall advantage.

8. Anticholinergics/COPD Agents

- New products – Lonhala Magnair (glycopyrrolate), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)
- New strength available for Daliresp (roflumilast)
- Different products may be more appropriate at different points of disease process or progression.

D. Executive Session

Audio Cast time -1:18:08 to 1:18:08

The Board recessed at 11:18 AM to review financial information relating to each of the eight therapeutic classes above. No official action was taken in the Executive Session. The Board reconvened to the public session at 11:56 AM.

Prior to the vote, it was announced publicly by the Chairperson that potential conflicts of interest had been identified and that where appropriate Board members would recuse themselves from the vote.

E. DUR Board PDP Recommendations

Audio Cast time -1:18:52 to 1:32:42

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
<p>Fluoroquinolones – Oral Audio Cast Time 1:30:19 to 1:23:48</p> <p>Preferred: Cipro (suspension), ciprofloxacin (tablet), levofloxacin (tablet)</p> <p>Non- Preferred: Avelox, Baxdela, Cipro (tablet) Cipro XR, ciprofloxacin ER, ciprofloxacin (suspension), Levaquin, levofloxacin (solution), moxifloxacin, ofloxacin</p> <p style="text-align: center;">Recommendation vote (14 members present) Passed unanimously</p>	<p>Approved as Recommended</p>
<p>Pulmonary Arterial Hypertension (PAH) Agents, Oral Audio Cast Time 1:23:53 to 1:24:51</p> <p>Preferred: Letairis, Tracleer (tablet)</p> <p>Non-Preferred: Adempas, Opsumit, Orenitram ER, Tracleer (suspension), Upravi</p> <p style="text-align: center;">Recommendation vote (14 members present) Passed unanimously</p>	<p>Approved as Recommended</p>

<p>Central Nervous System- Stimulants* Audio Cast Time 1:24:54 to 1:26:19</p> <p>Preferred: Adderall, Adderall XR, amphetamine salt combo IR, Aptensio XR, Daytrana, dextroamphetamine (tablet), Focalin, Focalin XR, Methylin (solution), methylphenidate (tablet), Quillivant XR, Vyvanse® (capsule, chewable tablet)</p> <p>Non-Preferred: Adzenys (XR-ODT, suspension), amphetamine salt combo ER, armodafinil, Concerta, Cotelpla XR-ODT, Desoxyn, Dexedrine, dexamethylphenidate, dexamethylphenidate ER (generic for Focalin XR), dextroamphetamine (solution), dextroamphetamine ER, Dyanavel XR, Evekeo, Metadate (CD, ER), methamphetamine, methylphenidate (chewable tablet, solution), methylphenidate CD (generic for Metadate CD), methylphenidate ER (generic Concerta), methylphenidate ER (generic Ritalin LA), methylphenidate ER (generic for Metadate ER), modafinil, Mydayis, Nuvigil, Procentra, Provigil, Quillichew ER, Ritalin, Ritalin LA, Zenzedi</p> <p style="text-align: center;">*Diagnosis confirmation, Age parameters, Quantity Limits</p> <p style="text-align: center;">Recommendation vote (14 members present) 13 yes 1 recusal</p>	<p>Approved as Recommended</p>
<p>Helicobacter Pylori Agents Audio Cast Time 1:26:22 to 1:23:47</p> <p>Preferred: Pylera</p> <p>Non-Preferred: lansoprazole/amoxicillin/clarithromycin (generic for Prevpac), Omeclamox-pak, Prevpac</p> <p style="text-align: center;">Recommendation vote (14 members present) 12 yes 2 no</p>	<p>Approved as Recommended</p>
<p>Immunomodulators- Systemic* Audio Cast Time 1:27:52 to 1:29:40</p> <p>Preferred: Cosentyx (pen, syringe), Enbrel, Enbrel cartridge, Humira</p> <p>Non-Preferred: Actemra (subcutaneous), Benlysta (subcutaneous), Cimzia, Kevzara (syringe, pen injector), Kineret, Olumiant, Orenzia (subcutaneous), Otezla, Siliq, Simponi, Stelara, Taltz, Tremfya, Xeljanz, Xeljanz XR</p> <p style="text-align: center;">*Diagnosis confirmation, Step therapy (trial of a DMARD).</p> <p style="text-align: center;">Recommendation vote (14 members present) 13 yes 1 recusal</p>	<p>Approved as Recommended</p>

<p>Ophthalmic Anti-inflammatory Agents* Audio Cast Time 1:29:53 to 1:31:02</p> <p>Preferred: Restasis, Restasis Multidose</p> <p>Non-Preferred: Xiidra</p> <p>*Diagnosis confirmation, Step therapy (trial of artificial tears or ocular lubricant), Quantity limits.</p> <p style="text-align: center;">Recommendation vote (14 members present) Passed unanimously</p>	<p>Approved as Recommended</p>
<p>Prostaglandin Agonists- Ophthalmics Audio Cast Time 1:31:06 to 1:31:42</p> <p>Preferred: latanoprost</p> <p>Non-Preferred: bimatoprost, Lumigan, Travatan Z, Vyzulta, Xalatan, Zioptan</p> <p style="text-align: center;">Recommendation vote (14 members present) Passed unanimously</p>	<p>Approved as Recommended</p>
<p>Anticholinergics-COPD Agents Audio Cast Time 1:31:44 to 1:32:37</p> <p>Preferred: Atrovent HFA®, Bevespi Aerosphere, Combivent Respimat, ipratropium, ipratropium/ albuterol, Spiriva, Stiolto Respimat</p> <p>Non-Preferred: Anoro Ellipta, Daliresp, Incruse Ellipta, Lonhala Magnair, Seebri Neohaler, Spiriva Respimat, Trelegy Ellipta, Tudorza Pressair, Utibron Neohaler</p> <p style="text-align: center;">Recommendation vote (14 members present) Passed unanimously</p>	<p>Approved as Recommended</p>

F. Drug Utilization Review: Prevention of Migraine Headaches

Audio Cast Time 1:34:10 to 2:07:59

Holly Coe, PharmD

This review focused on the preventive treatment of migraines including FDA-approved labeling and treatment guidelines. Utilization was evaluated and included data across each pharmacy management entity, including both fee-for-service (FFS) and managed care (MC) programs. The new drug Aimovig (erenumab), the first calcitonin gene-related peptide receptor antagonist, was evaluated. This evaluation focused on a literature review, with use of the drug primarily in clinical trials, since utilization and comparative data are absent or minimal. This literature review also included the ICER (Institute for Clinical and Economic Review) evidence report published July 2018

asserting that this class of agents lacks long-term efficacy and safety data and that it would be reasonable for payers to implement prior authorization criteria geared toward appropriate use of these agents.

The review began with an overview of the FDA approved products used in the pharmacologic management of prevention and acute treatment of migraines. Current guidelines were reviewed and compared along with safety warnings/precautions, adverse events and drug interactions associated with these drug therapies. Formulary status of treatment drugs was presented for New York as well as comparator states.

A utilization review of data for the treatment of migraines using preventive agents was presented for the period April 1, 2017 through March 31, 2018, and covered both FFS and MC programs. This review was inclusive of the parameters of member population encountered, number of claims received, claims per member, preventative agents used and duration of therapy.

Also presented was utilization data for agents for acute use in the treatment of migraines for the same period. The data found that the use of these agents for some members was above established recommended quantity limits. The findings suggested that these members may be candidates for preventive therapy.

The report concluded with the following recommendations:

1. Consider recommending use of a guideline-recommended preventive migraine agent for members who are exceeding the FFS-recommended monthly triptan quantity limits for at least 6 months.
2. Consider implementation of step therapy: patients must attempt at least 2 FDA-approved migraine prevention agents (divalproex, propranolol, timolol, or topiramate) prior to using erenumab (Aimovig™).
3. Consider quantity limits on the use of the new anti-migraine agent erenumab (Aimovig™).

The DUR Board recommended the following:

Prevention of Migraine Headaches	Audio Cast Time 2:08:00 to 2:24:30
DoH Recommendation #1:	
Step Therapy:	
	Trial of two (2) FDA approved migraine prevention products prior to a calcitonin gene-related peptide (CGRP) receptor antagonist.
	Recommendation Vote (15 members present) 14 Yes 1 recusal
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DoH Recommendation #2	
Quantity Limit Erenumab:	
	Maximum of two (2) prefilled syringes/autoinjectors per thirty (30) days.
	Recommendation Vote (15 members present) 14 yes 1 recusal
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Commissioner's Final Determination	
	Approved as Recommended

G. Hydroxyurea for Sickle Cell Disease

Audio Cast Time 2:24:40 to 3:12:10

Barbara Rogler, PharmD

This analysis was designed to determine the number of members in the NYS Medicaid Program with a diagnosis of sickle cell disease, to evaluate the utilization of hydroxyurea, and to explore emergency room and hospitalization rates for members with sickle cell disease.

An overall description of the disease prevalence, chronic complications and health care utilization within the Medicaid program was addressed as well as a review of the Expert Panel Report of 2014 which provided insight to evidence based management of sickle cell disease.

Multiple studies addressing the use of hydroxyurea in the treatment of sickle cell were presented. Studies addressed both adult and pediatric treatment.

A drug utilization review of members with the diagnosis of sickle cell disease within the Medicaid system was provided to the Board. The review included an estimate of the number of members within the Medicaid program diagnosed with the disease, an evaluation of the utilization of hydroxyurea for members with SCD continuously enrolled in the Medicaid Program, an evaluation of outpatient opioid utilization of those same members, calculations of the number of ER visits, inpatient hospitalization rates as well as readmission rates at 14 and 30 day periods for patients with SCD. This information provided the Board with a comparison of the hydroxyurea medication possession ratios (MPR) greater than or equal to 80% with that of members with an MPR less than 80 %. Results were presented along with a summary.

The presentation concluded with the following recommendations:

1. An enduring educational program should be developed to provide practitioners and pharmacists with an overview of the treatment of SCA, with an emphasis on the importance of hydroxyurea therapy. The program should have continuing education credit for both pharmacists and practitioners.
2. An educational letter outlining the benefits of hydroxyurea should be sent to practitioners.
3. Work collaboratively with MCOs to develop a standard report providing the MCOs with quarterly pharmacy utilization data.
4. Medicaid beneficiaries with SCD should be provided with a linkage to care. Patients with SCD should be linked to their Primary Care Provider and, when eligible, offered Health Home services to facilitate care management and care coordination. For members initiating and continuing hydroxyurea, a medication therapy management (MTM) program should be implemented.

The DUR Board recommended the following:

Hydroxyurea for Sickle Cell Disease	Audio Cast Time 3:12:22 to 3:14:27
DoH Recommendation:	
Targeted educational letter to prescribers highlighting the clinical utility of hydroxyurea for SCD.	
Recommendation Vote (15 members present) Passed unanimously	
Commissioner's Final Determination Approved as Recommended	

H. Clinical Editing Review

Due to time constraints this agenda item was postponed and will be addressed at a future meeting.

I. Final Comments and Adjournment

Douglas Fish, M.D. Chairperson
Anthony Merola, RPh, MBA

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

Meeting adjourned at 3:30 PM

J. 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 additional savings associated with these PDP therapeutic classes are estimated at \$307K. The savings are achieved through changes in utilization including the receipt of supplemental rebates from pharmaceutical manufacturers.