



New York State Medicaid Drug Utilization Review (DUR) Board Meeting Summary for October 19, 2017

The Medicaid DUR Board met on Thursday, October 19, 2017 from 9:00 AM to 4:00 PM Meeting Room 6, Concourse, Empire State Plaza, Albany, New York

An archived audio cast of the meeting proceedings is available on the Department of Health website: https://www.health.ny.gov/events/webcasts/2016/2016-09-15_dur.htm

A. Welcome and Introductions

(Audio Cast Time 00:28 - 05:52)

Department of Health

Janet Zachary-Elkind
Robert Correia, PharmD
Douglas Fish, MD
Anthony Merola, RPh, MBA

John Naioti, RPh
Robert Sheehan, RPh
Monica Toohey, RPh

DUR Board

Lisa Anzisi, PharmD
Nancy Balkon, PhD, NP
Donna Chiefari, PharmD
Marla Eglowstein, MD
Jacqueline Jacobi, RPh
Jill Lavigne, MPH, PhD
Peter Lopatka, FSA

Christopher Murphy, MD
Jadwiga Najib, PharmD
James Saperstone, MD
Tara Thomas, RPh, MBA
Maria Vullo, JD, MPA
John Wikiera

SUNY – University at Buffalo

Linda Catanzaro, PharmD
Barbara Rogler, PharmD, MS

Irene Reilly, PharmD

Magellan Medicaid Administration

Julie Gilbert, PharmD

B. Public Comment Period

(Audio Cast Time 05:52- 00:24:20)

The following speakers provided public comment to the board:

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| 1. Laurie Williams | Gilead Sciences | Hepatitis B Agents |
| 2. Laurie Williams | Gilead Sciences | Hepatitis C Agents – DAA |
| 3. Helen A. Adams, PA | Mt. Sinai Institute | Hepatitis C Agents – DAA |

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| 4. | Franco Casagrande, PharmD | AbbVie | Hepatitis C Agents – DAA |
| 5. | Tosin Tairu, PharmD, RPh | Merck & Co | Hepatitis C Agents – DAA |
| 6. | Jean C. McGrath Brodeur, PharmD | Pfizer | Atopic Dermatitis |

C. Preferred Drug Program (PDP) Reviews

Barbara Rogler, PharmD, MS
Julie Gilbert, PharmD
Robert Correia, PharmD

1. Hepatitis B Agents (Audio Cast Time 0:25:15)
 - Overview of Hepatitis B
 - Review of all drugs in the class inclusive of indications and adverse effects
 - Practice Guidelines - American Association for the Study of Liver Diseases (AASLD) and WHO – 2015
 - Review of comparative characteristics between the drugs in the class

2. Hepatitis C - Direct Acting Antivirals (DAA) (Audio Cast Time 0:42:30)
 - Overview of all products in the class inclusive of indications and adverse effects
 - New Products: Mavyret, Vosevi
 - Contraindications, Warnings, Adverse Reactions
 - Drug Interactions
 - Dosage and Administration
 - New Therapy Considerations
 - Updated guidance and recommendations for testing, managing and treating Hepatitis C
 - Review of utilization of DAAs in the NY Medicaid pharmacy program
 - Review of comparative characteristics between the products in the class

3. Glucocorticoids-oral (Audio Cast Time 02:09:10)
 - Overview of indications for all drugs in the class
 - New Products: Emflaza
 - Practice Guidelines- American College of Rheumatology, American Association for Hip and Knee Surgeons – 2017
 - Review of the comparative effectiveness review for Emflaza from the Drug Effectiveness Review Project (DERP) of the Oregon Health and Science University

4. Anti-Emetics (Audio Cast Time 02:21:25)
 - Review of all drugs added to the class
 - New Products: Akynzeo, Varubi, Diclegis
 - Practice Guidelines - American Academy of Clinical Oncology – 2015

- Practice Guidelines – American College of Gynecology
- Review of comparative characteristics of drugs in the class and subgroups of drugs in the class

D. Executive Session (Recess to Excessive Session Audio Cast Time 2:41:30)

The board recessed the public session at 12:00 PM to go into executive session for review of financial information relating to each of the PDP therapeutic classes under review. No official action was taken in the executive session. The board reconvened to the public session at 1:45 PM.

E. DUR Board Preferred Drug Program Recommendations

Based on the clinical and financial information, the board recommended the following to the Commissioner of Health for final determination:

| Recommendations of DUR Board | Commissioner's Final Determination |
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| <p>Hepatitis B Agents Audio Cast Time 2:44:23</p> <p>Preferred Baraclude Solution, Entecavir tablet, Epivir-HBV solution, Hepsera, lamivudine 100 mg tablet, Tyzeka</p> <p>Non-preferred adefovir dipivoxil, Baraclude tablet, Epivir-HBV tablet, Vemlidy</p> <p>Passed unanimously</p> | <p>Approved as Recommended</p> |
| <p>Hepatitis C - Direct Acting Antivirals (DAA) Audio Cast Time 2:46:00</p> <p>HCV DAA clinical criteria:</p> <ul style="list-style-type: none"> • FDA labeling and compendia supported use. • Prescriber experience and training. • Patient readiness and adherence. <p>Preferred Epclusa, Mavyret, ribavirin, Vosevi</p> <p>Non-preferred Copegus, Daklinza, Harvoni, Moderiba, Olysio, Rebetol, Ribasphere, Ribasphere/Ribapak, Sovaldi, Technivie, Viekira Pak, Viekira XR, Zepatier</p> <p>Passed unanimously</p> | <p>Approved as Recommended</p> |

| Recommendations of DUR Board | Commissioner's Final Determination |
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| <p>Glucocorticoids-oral Audio Cast Time 2:48:15</p> <p>Preferred dexamethasone tablet, hydrocortisone, methylprednisolone dose pak, prednisolone solution, prednisone dose pak and tablet.</p> <p>Non-preferred budesonide EC, cortisone, Cortef, dexamethasone solution and elixir, dexamethasone intensol, Dexpak, Emflaza, Entocort EC, Medrol dose pak and tablet, methylprednisolone 4mg, 8 mg, 16mg, 32mg tablets, Millipred, Orapred ODT, prednisolone ODT, prednisone intensol and solution, Rayos, Uceris, Veripred.</p> <p>Passed Unanimously</p> | <p>Approved as Recommended</p> |
| <p>Anti-Emetics Audio Cast Time 2:49:12</p> <p>Preferred ondansetron ODT, solution and tablet, Diclegis, Emend oral pack.</p> <p>Non-preferred Akynzeo, Anzemet, aprepitant capsule and pak, Emend capsule, powder and packet, granisetron tablet, Sancuso, Varubi, Zofran ODT, solution and tablet, Zuplenz.</p> <p>Passed Unanimously</p> | <p>Approved as Recommended</p> |

F. Drug Utilization Reviews (DUR)

(Audio Cast Time 2:50:50)

1. Management of Atopic Dermatitis

(Audio Cast Time 2:51:00 - 4:18:005)

A review of the management of Atopic Dermatitis (AD) was presented by Dr. Catanzaro. The presentation focused on the place in therapy of two new agents: crisaborole (Eucrisa) and dupilumab (Dupixent). Background information was presented addressing current FDA approved products for the treatment of AD. Management guidelines for the treatment of AD from the American Association of Dermatology as well as practice parameters from the Joint Task Force were referenced. Each of the new drugs were described relative to their involvement in clinical trials and adverse reactions. Utilization of both drugs was stratified by age,

diagnosis and the potential for requiring step therapy. Final recommendations were suggested for both agents in the form of step therapy and quantity limits.

The DUR Board recommended the following:

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| <p>Crisaborole (Eucrisa):</p> <p>Step therapy - For members 2 years of age or older with a diagnosis of an FDA-approved or compendia-supported indication.</p> <p>Trial with a prescription topical corticosteroid within the 3 months prior to prescribing of crisaborole.</p> <p>Absence of covered diagnosis or previous topical corticosteroid in patient's claim history will require prescriber involvement.</p> <p style="text-align: right;">Recommendation passed. Vote: Yes 12 No 1 Abstention 1</p> |
| <p>Crisaborole (Eucrisa):</p> <p>Quantity limit: 100 gm per 30 days.</p> <p style="text-align: right;">Recommendation passed. Vote: Yes 12 No 1 Abstention 1</p> |
| <p>Dupilumab (Dupixent):</p> <p>Step-therapy: For members 18 years of age or older with a diagnosis of an FDA-approved or compendia-supported indication.</p> <p>Trial required with a prescription topical corticosteroid of at least a medium or high potency and one other topical prescription agent other than a steroid (within a different class) indicated for Atopic Dermatitis for a combined duration of at least 6 months prior to the prescribing of dupilumab.</p> <p>Absence of covered diagnosis or previous topical corticosteroid in patient's claim history will require prescriber involvement.</p> <p style="text-align: right;">Recommendation passed. Vote: Yes 12 No 1 Abstention 1</p> |
| <p>Dupilumab (Dupixent):</p> <p>Quantity limit:</p> <p>2 cartons (each carton contains 2 pre-filled syringes) for first 30 days, followed by 1 carton per 30 days thereafter.</p> <p>Duration of any approval up to 4 months.</p> <p style="text-align: right;">Recommendation passed. Vote: Yes 12 No 1 Abstention 1</p> |

5. Management of Rosacea

(Audio Cast Time 4:18:40-4:52:40)

Dr. Reilly presented a drug utilization review of the management of rosacea. The review addressed the clinical pharmacology, efficacy and safety of the agents used in the treatment of rosacea. Utilization of these agents across the Medicaid and Medicaid Managed Care populations were stratified by age, gender, diagnosis, and drug. Drug products were presented respective to their FDA indication, pharmacology, dosage and administration, and safety parameters. Guidelines from the American Acne and Rosacea Society were presented to identify the place in therapy of the agents used in the treatment of rosacea. It was suggested that the Board consider for the treatment of rosacea the use of step therapy with the most cost-effective agents in conjunction with currently available treatment guidelines. In addition, consideration of a diagnosis requirement be rendered specific to the products Finacea, Mirvaso, Soolantra, Rhofade and Oracea.

The DUR Board (attendance reduced to 11 voting members) recommended the following:

Diagnosis requirement for Finacea (azelaic acid), Mirvaso (brimonidine), Soolantra (ivermectin), Rhofade (oxymetazoline HCl) and Oracea (doxycycline):

Confirm diagnosis for the FDA-approved or compendia-supported indications.

Absence of covered diagnosis or previous topical corticosteroid in patient's claim history will require prescriber involvement.

Recommendation passed. Vote: Yes 10 No 0 Abstention 1
(attendance reduced to 11 voting members)

Step therapy - For members with a diagnosis of rosacea:

Trial with most cost-effective agent(s) available considering treatment guidelines.

Recommendation passed. Vote: Yes 10 No 0 Abstention 1

Agenda items not addressed during this board meeting due to time constraints and to be reviewed at a future meeting:

- DUR of sedative hypnotics - evaluation of therapy duration
- DUR of codeine and tramadol - evaluation of safety
- DUR of methadone - evaluation in pain Management
- COPD and Influenza Vaccine Project

G. Final Comments and Adjournment

(Audio Cast Time 4:52:45 - 4:53:29)

Janet Zachary-Elkind
Anthony Merola, RPh, MBA
John Naioti, RPh

Meeting adjourned at 4:15 PM

H. 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 savings associated with these therapeutic classes under the PDP are estimated at \$1.4 million. The savings are achieved through changes in utilization including the receipt of supplemental rebates from pharmaceutical manufacturers.