New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for April 26, 2018

The Medicaid DUR Board met on Thursday, April 26, 2018 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: http://www.health.ny.gov/events/webcasts/

A. Welcome and Introductions

Audio Cast Time 00:12 - 04:20

Department of Health

Gregory Allen, MSW
Robert Correia, PharmD
Douglas Fish, MD
Anthony Merola, RPh, MBA
John Naioti, RPh
Robert Sheehan, RPh
Monica Toohey, RPh
Janet Zachary-Elkind, BA

DUR Board Members

Donna Chiefari, PharmD
James Hopsicker, RPh, MBA
Jacqueline Jacobi, RPh
Peter Lopatka, FSA
Christopher Murphy, MD
Jadwiga Najib, PharmD
Casey Quinn, PhD
Michelle Rainka, PharmD
James Saperstone, MD
Tara Thomas, RPh, MBA
Maria Vullo, JD, MPA

Magellan Medicaid Administration

Eileen Zimmer, PharmD, MBA

SUNY – University at Buffalo

Terry Dunn, PharmD
Barbara Rogler, PharmD, MS

Institute for Clinical and Economic Review

Sarah Emond, MPP
Dan Ollendorf, PhD
Steven D. Pearson, MD, MSc
Rick Chapman PhD, MS

B. Public Comment Period

Audio Cast Time 0:04:20 - 00:37:40

The following speakers provided public comment to the DUR Board:

1.	Jalpa Patel, PharmD	AstraZeneca	PP-4
2.	Olivia Lee, PharmD, MS	Boehringer-Ingelheim	DPP-4
3.	Niki Patel, PharmD, MBA	Novo Nordisk, Inc.	GLP-1 Agonists
4.	Niki Patel, PharmD, MBA	Novo Nordisk, Inc.	GLP-1 Agonists
5.	Patty Marchlowska, RN, BSN	Lilly USA	GLP-1 Agonists
6.	Jalpa Patel, PharmD	AstraZeneca	GLP-1 Agonists
7.	Jalpa Patel, PharmD	AstraZeneca	SGLT-2 Inhibitors
8.	Alanna Farrell-Foster	Merck	SGLT-2 Inhibitors
9.	Jawad Wunej, PharmD	Janssen Pharmaceuticals, Inc.	SGLT-2 Inhibitors
10.	Olivia Lee, PharmD, MS	Boehringer-Ingelheim	SGLT-2 Inhibitors
11.	Drucy Borowitz, MD	Cystic Fibrosis Foundation	Drug Cap
12.	Jamie Tobitt, PharmD	Vertex Pharmaceuticals	Drug Cap

C. Preferred Drug Program (PDP) Clinical Review

Audio Cast Time 0:37:40 - 1:12:02

Eileen Zimmer, PharmD, MBA
Robert Correia, PharmD

1. Cephalosporins – Third Generation
    - No new clinical information

2. Anti-Infectives – Topical
    - No new clinical information

3. Steroids, Topical - medium potency
    - No new clinical information

4. Steroids, Topical - high potency
    - No new clinical information

5. Dipeptidyl Peptidase-4 (DPP-4) Inhibitors
    - New Products: Steglujan (ertugliflozin/ sitagliptin); Qtern (dapagliflozin/saxagliptin)
    - Additional information: Practice guidelines (American College of Physicians, American Diabetes Association, American Association of Clinical Endocrinologists/American College of Endocrinology)
    - Review of meta-analysis supporting concept of comparability between the different drugs within the class
    - Identification of potential patient comorbidities or concomitant therapies that may impact drug selection

6. Glucagon-Like Peptide-1 (GLP-1) Agonists
    - New Products: Ozempic (semaglutide)
    - New Formulation: Bydureon BCise (exenatide extended release)
    - Additional New Information: FDA Communications (REMS eliminations on Trulicity, Xultophy and Tanzeum), clinical trials (Sustain3;6;7, Exscel)
    - Discontinuations: Tanzeum (albiglutide), Bydureon (exenatide) single dose tray
    - Review of information in practice guidelines, including recommendations pertaining to cardiovascular benefit
    - Review of potential impact of long acting and short acting products on fasting and postprandial blood glucose
    - Review of adverse effects profiles of the drugs within the class

7. Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors
    - New Products: Steglatro (ertugliflozin); Segluromet (ertugliflozin/ metformin)
    - New Formulation/Strengths: Synjardy XR (empagliflozin/metformin extended-release)
    - Additional Information: Practice guidelines, FDA Safety Communications, new clinical studies
    - Review of concerns relevant to risk for amputation and new studies suggestive of cardiovascular benefits as a class effect

8. Anticoagulants – Injectable
    - No new clinical information

9. Antihistamines – Ophthalmic
    - No new clinical information

10. Leukotriene Modifiers
    - No new clinical information

D. Executive Session Recess to Excessive Session - Audio Cast Time 1:12:02

The Board recessed to executive session at 10:25 AM to review financial information relating to each of the 10 therapeutic classes under review. No official action was taken in the executive session. The Board reconvened to the public session at 11:30 AM.

E. DUR Board PDP Recommendations

Audio Cast Time 1:12:10 – 1:20:30

Based on the 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
Cephalosporins – Third Generation Audio Cast Time 1:13:17 **Preferred**: cefdinir, Suprax **Non- Preferred**: cefixime, cefpodoxime Passed unanimously	Approved as Recommended
Anti-infectives – Topical Audio Cast Time 1:14:28 **Preferred:** clindamycin/benzoyl peroxide (generic for Duac), clindamycin (solution), erythromycin (solution) **Non-Preferred:** Acanya, BenzaClin (gel, pump), Benzamycin, Cleocin T, Clindacin, clindamycin (foam, gel, lotion, pledget), clindamycin/benzoyl peroxide (generic for BenzaClin), Duac, Erygel, erythromycin (gel, pledget), erythromycin/benzoyl peroxide, Evoclin, Neuac, Onexton Passed unanimously	Approved as Recommended
Steroids, Topical - medium potency Audio Cast Time 1:15:02 **Preferred:** mometasone furoate **Non-Preferred**: clocortolone, Cloderm, Cordran, Cutivate, Dermatop, Elocon, fluocinolone acetonide, flurandrenolide, fluticasone propionate, hydrocortisone butyrate, hydrocortisone valerate, Luxiq, Pandel, prednicarbate, Synalar Passed unanimously	Approved as Recommended

Steroids, Topical - high potency Audio Cast Time 1:15:46 **Preferred:** betamethasone dipropionate (cream, lotion), betamethasone valerate (cream, ointment), triamcinolone acetonide **Non-Preferred:** amcinonide, Apexicon-E, betamethasone dipropionate (gel, ointment), betamethasone dipropionate (augmented), betamethasone valerate (foam, lotion), desoximetasone, diflorasone, Diprolene, fluocinonide E, fluocinonide (cream, gel, solution, oint), Halog, Kenalog, Psorcon, Sernivo, Topicort, triamcinolone spray, Trianex, Vanos Passed unanimously	Approved as Recommended
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors* Audio Cast Time 1:16:25 **Preferred:** Glyxambi, Janumet, Janumet XR, Januvia, Jentadueto, Tradjenta **Non-Preferred:** alogliptin, alogliptin/metformin, alogliptin/pioglitazone, Jentadueto XR, Kombiglyze XR, Nesina, Onglyza Oseni, Qtern, Steglujan *Require a trial with metformin with or without insulin prior to DPP-4 Inhibitor therapy, unless there is a documented contraindication. Passed unanimously	Approved as Recommended
Glucagon-like Peptide-1 (GLP-1) Agents* Audio Cast Time 1:17:12 **Preferred:** Bydureon, Byetta, Victoza **Non-Preferred**: Adlyxin, Bydureon Bcise, Ozempic, Soliqua, Tanzeum, Trulicity, Xultophy *Requires a trial with metformin with or without insulin prior to a GLP-1 agonist, unless there is a documented contraindication. Absence of a covered diagnosis in patient's claim history will require prescriber involvement. Passed unanimously	Approved as Recommended

Sodium Glucose Co-Transporter 2 (SGLT-2) Inhibitors* Audio Cast Time 1:17:44 **Preferred:** Farxiga, Invokana, Jardiance **Non-Preferred**: Invokamet, Invokamet XR, Segluromet, Steglatro, Synjardy, Synjardy XR, Xigduo XR *Requires a trial with metformin with or without insulin prior to initiating SGLT-2 inhibitor therapy, unless there is a documented contraindication. Passed unanimously	Approved as Recommended
Anticoagulants – Injectable* Audio Cast Time 1:18:19 **Preferred:** enoxaparin sodium, Fragmin vial **Non-Preferred:** Arixtra**, fondaparinux, Fragmin syringe, Lovenox *For patients requiring >30 days of therapy: Require confirmation of FDA-approved or compendia-supported indication. Duration Limit: No more than 30 days for members initiating therapy. **Clinical editing to allow patients with a diagnosis of Heparin Induced Thrombocytopenia (HIT) to receive therapy without prior authorization. Passed unanimously	Approved as Recommended
Antihistamines - Ophthalmic Audio Cast Time 1:18:58 **Preferred:** Pazeo **Non-Preferred:** azelastine, Bepreve, Elestat, Emadine, epinastine, Lastacaft, olopatadine 0.1%, olopatadine 0.2%, Pataday, Patanol Passed unanimously	Approved as Recommended
Leukotriene Modifiers Audio Cast Time 1:19:24 **Preferred:** montelukast (tab, chewtab) * **Non-Preferred:** Accolate, montelukast granules*, Singular *, zafirlukast *For non-asthmatic patients, trial of intranasal corticosteroid or a second-generation oral antihistamine before montelukast (Singulair). Passed unanimously	Approved as Recommended

The Board recessed for lunch at 11:45AM. No official action was taken during the lunch break. The Board reconvened to the public session at 1:00PM.

F. Drug Cap – Orkambi (lumacaftor/ivacaftor)

Audio Cast Time 1:20:37 – 3:20:55

Janet Zachary Elkind, BA
Terry Dunn, PharmD
Steven Pearson, MD, MSc

Overview outlining the current status of the Drug Cap, the 2018-19 Budget process and the charge of the DUR Board with respect to the Drug Cap legislation.

Drug utilization review of Orkambi (lumacaftor/ivacaftor), and its use within the Medicaid Program. This included a background of the disease cystic fibrosis, the pharmacology and place in therapy of the drug Orkambi, a cost effectiveness analysis of the drug, price and coverage information encompassing the prevalence and utilization of Orkambi within the Medicaid program.

Institute of Clinical and Economic Review (ICER) report and value assessment of the drug Orkambi using the ICER Cost Effectiveness Analysis. A method overview was presented including a threshold price analysis based upon an expected range of quality-adjusted life years (QALY) modeled for the drug.

G. Executive Session

Recess to Excessive Session - Audio Cast Time 3:20:55

The Board recessed to executive session at 3:00 pm to review financial information relating to Orkambi (lumacaftor/ivacaftor). No official action was taken in the executive session. The Board reconvened to the public session at 3:45 PM.

H. DUR Board Drug Cap Recommendations

Audio Cast Time 3:21:00 - 3:22:32

Based on the 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
Drug Cap Review of Orkambi (lumacaftor/ivacaftor) Audio Cast Time 3:21:00 DoH Recommendation: Based on the unit price to achieve $150,000 per QALY threshold, the supplemental rebate target amount is the value resulting in a unit price equal to $56.94 (net of all rebates). Passed unanimously	Approved as Recommended

I. Final Comments and Adjournment

Audio Cast Time 3:22:32 - 3:25:33

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

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

Meeting adjourned at 4:05 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 savings associated with changes to the PDP therapeutic classes reviewed are estimated at $577,000. The savings would be achieved through changes in utilization including the receipt of supplemental rebates from pharmaceutical manufacturers.