

## **New York State Medicaid Drug Utilization Review (DUR) Board Meeting Summary for April 27, 2017**

The Medicaid DUR Board met on Thursday, April 27, 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: <http://www.health.ny.gov/events/webcasts/>

### **A. Welcome and Introductions**

(Audio Cast Time 00:01 - 03:00)

#### Department of Health

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

John Naioti, RPh  
 Alda Osinaga, MD  
 Robert Sheehan, RPh  
 Monica Toohey, RPh

#### DUR Board Members

Lisa Anzisi, PharmD  
 Nancy Balkon, PhD, NP  
 Donna Chiefari, PharmD  
 Marla Eglowstein, MD  
 James Hopsicker, RPh, MBA  
 Christopher Murphy, MD

Jadwiga Najib, PharmD  
 Paula Panzer, MD  
 Asa Radix, MD  
 James Saperstone, MD  
 Tara Thomas, RPh, MBA

#### Magellan Medicaid Administration

Eileen Zimmer, PharmD, MBA

### **B. Public Comment Period**

(Audio Cast Time 03:00 - 01:20:47)

The following speakers provided public comment to the Board:

- |                                     |                             |                                     |
|-------------------------------------|-----------------------------|-------------------------------------|
| 1. Laurel Raines, MS, MPAS, PA-C    | Purdue Pharma LP            | Opioids – Long-Acting               |
| 2. Michelle Del Corral, PharmD, MBA | Pfizer Inc.                 | Opioids – Long-Acting               |
| 3. David E Chapman, PhD             | UCB, Inc.                   | Anticonvulsants – Second Generation |
| 4. J. Phillip Jennings, PharmD      | Allergan PLC                | Antipsychotics – Second Generation  |
| 5. Michael A. Nelson PharmD         | Sunovion Pharmaceuticals    | Antipsychotics – Second Generation  |
| 6. Ben Skoog, PharmD                | Acadia Pharmaceuticals Inc. | Antipsychotics – Second Generation  |
| 7. Matthew Shapiro                  | NAMI-NYS                    | Antipsychotics – Second Generation  |

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|-----|-----------------------------|----------------------------------|--------------------------------|
| 8.  | Meleik A. Hebert, PhD       | Pfizer Inc.                      | CNS Stimulants                 |
| 9.  | Michael Feld, MD            | Rhodes Pharmaceuticals LP        | CNS Stimulants                 |
| 10. | Mark S. Owens, DO           | Neos Therapeutics, Inc.          | CNS Stimulants                 |
| 11. | Tyson S. Park, PharmD       | Teva Pharmaceuticals USA         | Multiple Sclerosis Agents      |
| 12. | Franco Casagrande, PharmD   | Abbvie                           | Multiple Sclerosis Agents      |
| 13. | David Strand                | Novo Nordisk, Inc.               | GLP-1 Agonists                 |
| 14. | Laura McClung, PhD          | Eli Lilly and Co                 | GLP-1 Agonists                 |
| 15. | Jalpa K. Patel, PharmD      | AstraZeneca                      | GLP-1 Agonists                 |
| 16. | Alan Chant, BS, PharmD      | Sanofi US                        | GLP-1 Agonists                 |
| 17. | Laura McClung, PhD          | Eli Lilly and Co                 | Insulin – Long-Acting          |
| 18. | David Strand                | Novo Nordisk, Inc.               | Insulin – Long-Acting          |
| 19. | Arlene R. Price, PharmD     | Janssen Scientific Affairs, Inc. | SGLT 2 Inhibitors              |
| 20. | Jalpa K. Patel, PharmD      | AstraZeneca                      | SGLT-2 Inhibitors              |
| 21. | Mehak Talwar, PharmD        | Boehringer Ingelheim             | SGLT-2 Inhibitors              |
| 22. | Arlene R. Price, PharmD     | Janssen Scientific Affairs, Inc. | Anticoagulants - Oral          |
| 23. | Francis S Lobo, BS, MS, PhD | Bristol-Myers Squibb             | Anticoagulants - Oral          |
| 24. | Mehak Talwar, PharmD        | Boehringer Ingelheim             | Anticoagulants - Oral          |
| 25. | Jalpa K. Patel, PharmD      | AstraZeneca                      | Platelet Inhibitors            |
| 26. | Lily Chan, PharmD           | Sunovion Pharmaceuticals         | Anticholinergics – COPD Agents |
| 27. | Jalpa K. Patel, PharmD      | AstraZeneca                      | Anticholinergics – COPD Agents |
| 28. | Mehak Talwar, PharmD        | Boehringer Ingelheim             | Anticholinergics – COPD Agents |

### C. Preferred Drug Program Clinical Reviews

(Audio Cast Time 1:21:26 - 2:32:18)

Eileen Zimmer, PharmD, MBA  
Robert Correia, PharmD

1. Opioids – Long Acting (Audio Cast Time 1:23:40)
  - New product: Xtampza ER (oxycodone ER)
  - Additional information – FDA communications, practice guidelines
  
2. Angiotensin Converting Enzyme Inhibitors (ACEIs) (Audio Cast Time 1:32:32)
  - New formulation: Qbrelis (lisinopril oral solution), Epaned (enalapril oral solution)
  - Label revision: Prinivil (lisinopril)
  - Additional information - Practice guidelines
  
3. HMG-CoA Reductase Inhibitors (Statins) (Audio Cast Time 1:36:03)
  - New indication: Crestor (rosuvastatin)
  - Additional information – practice guidelines
  
4. Anticonvulsants
  - No new clinical information

5. Second Generation Antipsychotics (Audio Cast Time 1:39:26)
  - New product: Nuplazid (pimavanserin)
  - Label revision: class effect warning, addition of DRESS to Seroquel (quetiapine) and Seroquel XR (quetiapine XR) post marketing
  - New indication: Latuda (lurasidone), Saphris (asenapine)
  - Additional information – practice guidelines, FDA communications
6. Central Nervous System (CNS) Stimulants
  - No new clinical information
7. Multiple Sclerosis Agents
  - No new clinical information
8. Anti-Fungals – Topical
  - No new clinical information
9. Anti-Infectives – Topical
  - No new clinical information
10. GLP-1 Agonists (Audio Cast Time 1:45:37)
  - New product: Xultophy (liraglutide/insulin degludec), Adlyxin (lixisenatide), Soliqua (lixisenatide/insulin glargine)
  - Additional information – practice guidelines, clinical studies
11. Insulins, Long – Acting (Audio Cast Time 1:57:10)
  - New product: Basaglar (insulin glargine)
  - New indication: Tresiba (insulin degludec)
  - Additional information – practice guidelines
12. SGLT2 Inhibitors (Audio Cast Time 2:05:14)
  - New formulation: Invokamet XR (canagliflozin/metformin XR)
  - New indication: Jardiance (empagliflozin), Synjardy (empagliflozin/metformin)
  - Additional information – practice guidelines, FDA communications
13. Anticoagulants – Oral
  - No new clinical information
14. Platelet Inhibitors
  - No new clinical information
15. Epinephrine, Self-Injected (Audio Cast Time 2:10:12)
  - Background information respective to anaphylaxis and its treatment
  - FDA-approved indications
  - Prescribing information
  - Place in therapy

- 16. Non-Steroidal Anti-inflammatory Drugs (NSAIDs) – Ophthalmic (Audio Cast Time 2:14:57)
  - New product: BromSite (bromfenac 0.075% solution)
- 17. Fluoroquinolones – Otic (Audio Cast Time 2:17:37)
  - New product: Otovel (ciprofloxacin/fluocinolone)
- 18. Phosphate Binders/Regulators (Audio Cast Time 2:20:25)
  - New indication: Renvela (sevelamer)
- 19. Anticholinergics – COPD Agents (Audio Cast Time 2:22:44)
  - New drug: Bevespi Aerosphere (glycopyrrolate/formoterol)
  - New indication: Spiriva Respimat (tiotropium)
  - Additional information – practice guidelines
- 20. Corticosteroids/LABA Combinations – Inhaled (Audio Cast Time 2:28:50)
  - New indication: Breo Ellipta (fluticasone/vilanterol), Symbicort (budesonide/formoterol)
  - Additional information – practice guidelines
- 21. Corticosteroids – Intranasal
  - No new clinical information

**E. Executive Session**

(Recess to Excessive Session - Audio Cast Time 2:32:18)

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 therapeutic classes under review. No official action was taken in the executive session. The Board reconvened to the public session at 2:15 pm.

**F. DUR Board Recommendations**

(Audio Cast Time 2:33:13 – 2:55:30)

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 |
|--|------------------------------------|
| <p><b>Opioids – Long Acting</b> <span style="float: right;">Audio Cast Time 2:35:06</span></p> <p><b>Preferred:</b> Butrans, Embeda ER, fentanyl patch (12mcg, 25mcg, 50mcg, 75mcg, 100mcg), morphine sulfate SR (tablet)</p> <p><b>Non- Preferred:</b> Belbuca, Conzip, Duragesic, Exalgo, fentanyl patch (37.5mcg, 62.5mcg, 87.5mcg), hydromorphone ER, Hysingla ER, Kadian, morphine ER capsule (generic for Avinza), morphine ER capsule (generic for Kadian), MS Contin, Nucynta ER, Opana ER, oxycodone ER, Oxycontin, oxymorphone ER, tramadol ER, Xtampza ER, Zohydro ER</p> <p style="text-align: center;">Passed Unanimously</p> | <p>Approved as Recommended</p>     |

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| <p><b>Angiotensin Converting Enzyme Inhibitors (ACEIs)</b> <span style="float: right;">Audio Cast Time 2:36:07</span></p> <p><b>Preferred:</b> benazepril, enalapril, lisinopril, ramipril</p> <p><b>Non-Preferred:</b> Accupril, Altace, captopril, Epaned, fosinopril, Lotensin, Mavik, moexipril, perindopril, Prinivil, Qbrelis, quinapril, trandolapril, Vasotec, Zestril</p> <p style="text-align: center;">Passed Unanimously</p>  | <p>Approved as Recommended</p> |
| <p><b>HMG-CoA Reductase Inhibitors (Statins)</b> <span style="float: right;">Audio Cast Time 2:36:42</span></p> <p><b>Preferred:</b> atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin</p> <p><b>Non-Preferred:</b> Altoprev, atorvastatin/amlodipine, Caduet, Crestor, fluvastatin, fluvastatin ER, Lescol XL, Lipitor, Livalo, Pravachol, Vytorin, Zocor</p> <p style="text-align: center;">Passed Unanimously</p>   | <p>Approved as Recommended</p> |
| <p><b>Anticonvulsants – Second Generation</b> <span style="float: right;">Audio Cast Time 2:37:18</span></p> <p><b>Preferred:</b> gabapentin (capsule, solution), lamotrigine, levetiracetam, levetiracetam ER, Lyrica (capsule), tiagabine, topiramate, zonisamide</p> <p><b>Non-Preferred:</b> Banzel, Briviact, felbamate*, Felbatol, Fycompa, gabapentin (tablet), Gabitril, Keppra, Keppra XR, Lamictal, Lamictal ODT, Lamictal XR, lamotrigine XR, lamotrigine ODT, Lyrica (solution)*, Neurontin, Onfi, Potiga, Qudexy XR, Sabril, Spritam, Topamax, topiramate ER, Trokendi XR, Vimpat, Zonegran</p> <p style="text-align: center;">*Automated prior authorization bypass for patients stabilized on a product(s) moving to non-preferred status.</p> <p style="text-align: center;">Passed Unanimously</p> | <p>Approved as Recommended</p> |

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| <p><b>Antipsychotics – Second Generation</b> <span style="float: right;">Audio Cast Time 2:39:00</span></p> <p><b>Preferred:</b> aripiprazole (solution, tablet), clozapine, Latuda, olanzapine (tablet), quetiapine, risperidone, Saphris, Seroquel XR, ziprasidone</p> <p><b>Non-Preferred:</b> Abilify (solution, tablet), aripiprazole ODT, clozapine ODT, Clozaril, Fanapt*, FazaClo, Geodon, Invega, Nuplazid, olanzapine ODT, paliperidone ER, quetiapine ER, Rexulti, Risperdal, Seroquel, Versacloz, Vraylar, Zyprexa</p> <p style="text-align: center;">*Automated prior authorization bypass for patients stabilized on a product(s) moving to non-preferred status.</p> <p style="text-align: center;">Passed Unanimously</p>   | <p>Approved as Recommended</p> |
| <p><b>Central Nervous System (CNS) Stimulants</b> <span style="float: right;">Audio Cast Time 2:39:35</span></p> <p><b>Preferred:</b> Adderall, Adderall XR, amphetamine salt combo IR, Daytrana, dextroamphetamine tablet, Focalin XR, Focalin, Methylin (chewable, solution), methylphenidate (tablet), Quillivant XR, Vyvanse (capsule)</p> <p><b>Non-preferred:</b> Adzenys XR ODT, amphetamine salt combo ER, Aptensio XR, armodafinil, Concerta, Desoxyn, Dexedrine, dextroamphetamine (solution), dextroamphetamine ER, dexmethylphenidate ER (generic for Focalin XR), dexmethylphenidate, Dyanavel XR, Evekeo, Metadate CD, Metadate ER, methamphetamine, methylphenidate CD (generic for Metadate CD), methylphenidate ER (generic for Concerta), methylphenidate ER (generic for Ritalin LA), methylphenidate (chewable, solution), methylphenidate SR (generic for Metadate ER), modafinil, Nuvigil, Procentra, Provigil, Quillichew ER, Ritalin, Ritalin LA, Vyvanse (chewable), Zenzedi</p> <p style="text-align: center;">Passed Unanimously</p> | <p>Approved as Recommended</p> |
| <p><b>Multiple Sclerosis Agents</b> <span style="float: right;">Audio Cast Time 2:40:48</span></p> <p><b>Preferred:</b> Avonex, Betaseron, Copaxone 20 mg/ml, Gilenya*, Rebif</p> <p><b>Non-Preferred:</b> Aubagio, Copaxone 40 mg/ml, Extavia, Glatopa, Plegridy, Tecfidera, Zinbryta</p> <p style="text-align: center;">*Requires trial with a preferred injectable product.</p> <p style="text-align: center;">Passed Unanimously</p>  | <p>Approved as Recommended</p> |

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| <p><b>Anti-Fungals – Topical</b> <span style="float: right;">Audio Cast Time 2:41:28</span></p> <p><b>Preferred:</b> ciclopirox (cream, topical suspension), clotrimazole OTC (solution, cream), clotrimazole/betamethasone cream, miconazole OTC (cream, ointment, powder, spray), Nyamyc, nystatin (cream, ointment, powder), Nystop, terbinafine OTC, tolnaftate OTC</p> <p><b>Non-Preferred:</b> Alevazol OTC, Ciclodan (cream), ciclopirox (gel), clotrimazole/betamethasone lotion, clotrimazole Rx (cream, solution), econazole, Ertaczo, Exelderm, Extina, ketoconazole, Lamisil AT (spray), Lotrisone, Luzu, Mentax, naftifine, Naftin, nystatin/triamcinolone, oxiconazole, Oxistat, Vusion</p> <p style="text-align: center;">Passed Unanimously</p> | <p>Approved as Recommended</p> |
| <p><b>Anti-Infectives – Topical</b> <span style="float: right;">Audio Cast Time 2:42:14</span></p> <p><b>Preferred:</b> BenzaClin (pump, gel), clindamycin (solution), erythromycin (solution)</p> <p><b>Non-Preferred:</b> Acanya, Benzamycin, Cleocin T, Clindacin, Clindagel, clindamycin (gel, foam, lotion, pledget), clindamycin/benzoyl peroxide, Duac, Erygel, erythromycin (gel, pledget), erythromycin/benzoyl peroxide, Evoclin, Neuac, Onexton</p> <p style="text-align: center;">Passed Unanimously</p>  | <p>Approved as Recommended</p> |
| <p><b>Glucagon-like Peptide –1 (GLP-1) Agents</b> <span style="float: right;">Audio Cast Time 2:42:47</span></p> <p><b>Preferred:</b> Bydureon, Byetta, Victoza</p> <p><b>Non-Preferred:</b> Adlyxin, Soliqua, Tanzeum, Trulicity, Xultophy</p> <p style="text-align: center;">Passed Unanimously</p>   | <p>Approved as Recommended</p> |
| <p><b>Insulin – Long Acting</b> <span style="float: right;">Audio Cast Time 2:43:16</span></p> <p><b>Preferred:</b> Lantus, Levemir</p> <p><b>Non-Preferred:</b> Basaglar, Toujeo, Tresiba</p> <p style="text-align: center;">Passed Unanimously</p>  | <p>Approved as Recommended</p> |

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| <p><b>Sodium Glucose Co-Transporter 2 (SGLT-2) Inhibitors</b> <span style="float: right;">Audio Cast Time 2:43:42</span></p> <p><b>Preferred:</b> Farxiga, Invokana</p> <p><b>Non-Preferred:</b> Invokamet, Invokamet XR, Jardiance, Synjardy, Xigduo XR</p> <p style="text-align: center;">Passed Unanimously</p>   | <p style="text-align: center;">Approved as Recommended</p> |
| <p><b>Anticoagulants – Oral</b> <span style="float: right;">Audio Cast Time 2:44:08</span></p> <p><b>Preferred:</b> Coumadin, Eliquis, Jantoven, Pradaxa, warfarin, Xarelto</p> <p><b>Non-Preferred:</b> Savaysa, Xarelto (dose pak)</p> <p style="text-align: center;">Passed Unanimously</p>   | <p style="text-align: center;">Approved as Recommended</p> |
| <p><b>Platelet Inhibitors</b> <span style="float: right;">Audio Cast Time 2:44:32</span></p> <p><b>Preferred:</b> Aggrenox, Brilinta, clopidogrel, dipyridamole</p> <p><b>Non-Preferred:</b> dipyridamole/aspirin, Durlaza, Effient, Plavix, ticlopidine, Yosprala, Zontivity</p> <p style="text-align: center;">Passed Unanimously</p>  | <p style="text-align: center;">Approved as Recommended</p> |
| <p><b>Epinephrine, Self-injected</b> <span style="float: right;">Audio Cast Time 2:45:01</span></p> <p><b>Preferred:</b> epinephrine pen 0.3mg (generic Epi-pen), epinephrine pen 0.15mg (generic Epi-pen Jr.)</p> <p><b>Non-Preferred:</b> Adrenaclick, EpiPen, EpiPen Jr., epinephrine pen (generic Adrenaclick)</p> <p style="text-align: center;">Passed Unanimously</p>         | <p style="text-align: center;">Approved as Recommended</p> |
| <p><b>Non-Steroidal Anti-inflammatory Drugs (NSAIDs) – Ophthalmic</b> <span style="float: right;">Audio Cast Time 2:45:33</span></p> <p><b>Preferred:</b> diclofenac, flurbiprofen, ketorolac/ketorolac LS, Ilevro</p> <p><b>Non-Preferred:</b> Acular, Acular LS, Acuvail, bromfenac, BromSite, Nevanac, Ocufer, Prolensa</p> <p style="text-align: center;">Passed Unanimously</p> | <p style="text-align: center;">Approved as Recommended</p> |



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| <p><b>Fluoroquinolones – Otic</b> <span style="float: right;">Audio Cast Time 2:46:00</span></p> <p><b>Preferred:</b> Cipro HC, Ciprodex, ciprofloxacin</p> <p><b>Non-Preferred:</b> Floxin, ofloxacin, Otovel</p> <p style="text-align: center;">Passed Unanimously</p>  | <p>Approved as Recommended</p> |
| <p><b>Phosphate Binders/Regulators</b> <span style="float: right;">Audio Cast Time 2:46:19</span></p> <p><b>Preferred:</b> calcium acetate, Eliphos, Fosrenol, Renagel</p> <p><b>Non-Preferred:</b> Auryxia, Phoslyra, Renvela, Velphoro</p> <p style="text-align: center;">Passed Unanimously</p>  | <p>Approved as Recommended</p> |
| <p><b>Anticholinergics/COPD Agents</b> <span style="float: right;">Audio Cast Time 2:46:43</span></p> <p><b>Preferred:</b> Atrovent HFA, Combivent Respimat, ipratropium, ipratropium/albuterol, Spiriva, Stiolto Respimat</p> <p><b>Non-Preferred:</b> Anoro Ellipta, Bevespi Aerosphere, Daliresp, Incruse Ellipta, Seebri Neohaler, Spiriva Respimat, Tudorza Pressair, Utibron Neohaler</p> <p style="text-align: center;">Passed Unanimously</p>                       | <p>Approved as Recommended</p> |
| <p><b>Corticosteroid/Beta-2 Adrenergic Agent (Long Acting) Combinations – Inhaled</b> <span style="float: right;">Audio Cast Time 2:47:38</span></p> <p><b>Preferred:</b> Advair Diskus, Dulera, Symbicort</p> <p><b>Non-Preferred:</b> Advair HFA, Breo Ellipta</p> <p style="text-align: center;">11 in favor, 1 opposed, 0 abstentions</p>   | <p>Approved as Recommended</p> |
| <p><b>Corticosteroids – Intranasal</b> <span style="float: right;">Audio Cast Time 2:50:33</span></p> <p><b>Preferred:</b> fluticasone</p> <p><b>Non-Preferred:</b> Beconase AQ*, budesonide, Dymista, flunisolide, mometasone, Nasonex, Omnaris, QNASL*, Veramyst, Zetonna</p> <p>*Beclomethasone automated prior authorization bypass for patients with established HIV/AIDS diagnosis or indicative treatment.</p> <p style="text-align: center;">Passed Unanimously</p> | <p>Approved as Recommended</p> |

## **G. Final Comments and Adjournment**

(Audio Cast Time 2:55:30 - 2:56:50)

Janet Zachary-Elkind, Deputy Director

Anthony Merola, RPh, MBA

Contact for post meeting questions: [DUR@health.ny.gov](mailto:DUR@health.ny.gov) or 518-486-3209

## **Meeting adjourned at 2:45 PM**

## **H. Commissioner's Final Determinations**

The impact of the final determination is as follows:

1. 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.
2. Program Providers:
  - Minimal impact on prescribers when utilizing preferred products. Prescribers, or their agents, will need to initiate the prior authorization process when ordering non-preferred products.
3. State Health Program:
  - Annual gross savings associated with modifications to the Preferred Drug List (PDL) are estimated at \$3.1M. The savings are achieved through receipt of supplemental rebates from pharmaceutical manufacturers and changes in utilization to equally effective and less expensive products.