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         John Naioti, RPh
Robert Correia, PharmD                        Alda Osinaga, MD
Douglas Fish, MD                             Robert Sheehan, RPh
Anthony Merola, RPh, MBA                     Monica Toohey, RPh

DUR Board Members
Lisa Anzisi, PharmD                           Jadwiga Najib, PharmD
Nancy Balkon, PhD, NP                        Paula Panzer, MD
Donna Chiefari, PharmD                       Asa Radix, MD
Marla Eglowstein, MD                         James Saperstone, MD
James Hopsicker, RPh, MBA                    Tara Thomas, RPh, MBA
Christopher Murphy, MD

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
7. Matthew Shapiro                            NAMI-NYS              Antipsychotics – Second Generation
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<th></th>
<th>Name</th>
<th>Company</th>
<th>Drug Class</th>
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</thead>
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<tr>
<td>8.</td>
<td>Meleik A. Hebert, PhD</td>
<td>Pfizer Inc.</td>
<td>CNS Stimulants</td>
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<td>9.</td>
<td>Michael Feld, MD</td>
<td>Rhodes Pharmaceuticals LP</td>
<td>CNS Stimulants</td>
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<td>10.</td>
<td>Mark S. Owens, DO</td>
<td>Neos Therapeutics, Inc.</td>
<td>CNS Stimulants</td>
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<td>11.</td>
<td>Tyson S. Park, PharmD</td>
<td>Teva Pharmaceuticals USA</td>
<td>Multiple Sclerosis Agents</td>
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<td>12.</td>
<td>Franco Casagrande, PharmD</td>
<td>Abbvie</td>
<td>Multiple Sclerosis Agents</td>
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<td>13.</td>
<td>David Strand</td>
<td>Novo Nordisk, Inc.</td>
<td>GLP-1 Agonists</td>
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<td>14.</td>
<td>Laura McClung, PhD</td>
<td>Eli Lilly and Co</td>
<td>GLP-1 Agonists</td>
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<td>15.</td>
<td>Jalpa K. Patel, PharmD</td>
<td>AstraZeneca</td>
<td>GLP-1 Agonists</td>
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<td>16.</td>
<td>Alan Chant, BS, PharmD</td>
<td>Sanofi US</td>
<td>GLP-1 Agonists</td>
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<td>17.</td>
<td>Laura McClung, PhD</td>
<td>Eli Lilly and Co</td>
<td>Insulin – Long-Acting</td>
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<td>18.</td>
<td>David Strand</td>
<td>Novo Nordisk, Inc.</td>
<td>Insulin – Long-Acting</td>
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<td>19.</td>
<td>Arlene R. Price, PharmD</td>
<td>Janssen Scientific Affairs, Inc.</td>
<td>SGLT 2 Inhibitors</td>
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<td>20.</td>
<td>Jalpa K. Patel, PharmD</td>
<td>AstraZeneca</td>
<td>SGLT-2 Inhibitors</td>
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<td>21.</td>
<td>Mehak Talwar, PharmD</td>
<td>Boehringer Ingelheim</td>
<td>SGLT-2 Inhibitors</td>
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<td>23.</td>
<td>Francis S Lobo, BS, MS, PhD</td>
<td>Bristol-Myers Squibb</td>
<td>Anticoagulants - Oral</td>
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<td>24.</td>
<td>Mehak Talwar, PharmD</td>
<td>Boehringer Ingelheim</td>
<td>Anticoagulants - Oral</td>
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<td>25.</td>
<td>Jalpa K. Patel, PharmD</td>
<td>AstraZeneca</td>
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<td>26.</td>
<td>Lily Chan, PharmD</td>
<td>Sunovion Pharmaceuticals</td>
<td>Anticholinergics – COPD Agents</td>
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<td>27.</td>
<td>Jalpa K. Patel, PharmD</td>
<td>AstraZeneca</td>
<td>Anticholinergics – COPD Agents</td>
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<td>28.</td>
<td>Mehak Talwar, PharmD</td>
<td>Boehringer Ingelheim</td>
<td>Anticholinergics – COPD Agents</td>
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C. Preferred Drug Program Clinical Reviews
Eileen Zimmer, PharmD, MBA
Robert Correia, PharmD

1. Opioids – Long Acting
   - New product: Xtampza ER (oxycodone ER)
   - Additional information – FDA communications, practice guidelines

2. Angiotensin Converting Enzyme Inhibitors (ACEIs)
   - New formulation: Qbrelis (lisinopril oral solution), Epaned (enalapril oral solution)
   - Label revision: Prinivil (lisinopril)
   - Additional information - Practice guidelines

3. HMG-CoA Reductase Inhibitors (Statins)
   - New indication: Crestor (rosuvastatin)
   - Additional information – practice guidelines

4. Anticonvulsants
   - No new clinical information
5. Second Generation Antipsychotics
   - 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
    - New product: Xultophy (liraglutide/insulin degludec), Adlyxin (lixisenatide), Soliqua (lixisenatide/insulin glargine)
    - Additional information – practice guidelines, clinical studies

11. Insulins, Long – Acting
    - New product: Basaglar (insulin glargine)
    - New indication: Tresiba (insulin degludec)
    - Additional information – practice guidelines

12. SGLT2 Inhibitors
    - 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
    - Background information respective to anaphylaxis and its treatment
    - FDA-approved indications
    - Prescribing information
    - Place in therapy
16. Non-Steroidal Anti-inflammatory Drugs (NSAIDs) – Ophthalmic
   • New product: BromSite (bromfenac 0.075% solution)

17. Fluoroquinolones – Otic
   • New product: Otovel (ciprofloxacin/fluocinolone)

18. Phosphate Binders/Regulators
   • New indication: Renvela (sevelamer)

19. Anticholinergics – COPD Agents
   • New drug: Bevespi Aerosphere (glycopyrrolate/formoterol)
   • New indication: Spiriva Respimat (tiotropium)
   • Additional information – practice guidelines

20. Corticosteroids/LABA Combinations – Inhaled
   • 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:

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<tr>
<th>Recommendations of the DUR Board</th>
<th>Commissioner's Final Determination</th>
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<tr>
<td><strong>Opioids – Long Acting</strong></td>
<td><strong>Passed Unanimously</strong></td>
</tr>
<tr>
<td>Preferred: Butrans, Embeda ER, fentanyl patch (12mcg, 25mcg, 50mcg, 75mcg, 100mcg), morphine sulfate SR (tablet)</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td>Non- Preferred: 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</td>
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Audio Cast Time 2:35:06
### Angiotensin Converting Enzyme Inhibitors (ACEIs)

**Preferred:** benazepril, enalapril, lisinopril, ramipril  
**Non-Preferred:** Accupril, Altace, captopril, Epaned, fosinopril, Lotensin, Mavik, moexipril, perindopril, Prinivil, Qbrelis, quinapril, trandolapril, Vasotec, Zestril  
Passed Unanimously  
Approved as Recommended

### HMG-CoA Reductase Inhibitors (Statins)

**Preferred:** atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin  
**Non-Preferred:** Altoprev, atorvastatin/amlodipine, Caduet, Crestor, fluvastatin, fluvastatin ER, Lescol XL, Lipitor, Livalo, Pravachol, Vytorin, Zocor  
Passed Unanimously  
Approved as Recommended

### Anticonvulsants – Second Generation

**Preferred:** gabapentin (capsule, solution), lamotrigine, levetiracetam, levetiracetam ER, Lyrica (capsule), tiagabine, topiramate, zonisamide  
**Non-Preferred:** 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, Vimgat, Zonegran  
*Automated prior authorization bypass for patients stabilized on a product(s) moving to non-preferred status.  
Passed Unanimously  
Approved as Recommended
### Antipsychotics – Second Generation

**Preferred:** aripiprazole (solution, tablet), clozapine, Latuda, olanzapine (tablet), quetiapine, risperidone, Saphris, Seroquel XR, ziprasidone

**Non-Preferred:** Abilify (solution, tablet), aripiprazole ODT, clozapine ODT, Clozaril, Fanapt*, FazaClo, Geodon, Invega, Nuplazid, olanzapine ODT, paliperidone ER, quetiapine ER, Rexulti, Risperdal, Seroquel, Versacloz, Vraylar, Zy prexa

* *Automated prior authorization bypass for patients stabilized on a product(s) moving to non-preferred status.

Passed Unanimously

### Central Nervous System (CNS) Stimulants

**Preferred:** Adderall, Adderall XR, amphetamine salt combo IR, Daytrana, dextroamphetamine tablet, Focalin XR, Focalin, Methylin (chewable, solution), methylphenidate (tablet), Quillivant XR, Vyvanse (capsule)

**Non-preferred:** 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), Zenedi

Passed Unanimously

### Multiple Sclerosis Agents

**Preferred:** Avonex, Betaseron, Copaxone 20 mg/ml, Gilenya*, Rebif

**Non-Preferred:** Aubagio, Copaxone 40 mg/ml, Extavia, Glatopa, Plegridy, Tecfidera, Zinbryta

*Requires trial with a preferred injectable product.

Passed Unanimously
### Anti-Fungals – Topical

**Preferred:** 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

**Non-Preferred:** Alevazol OTC, Ciclodan (cream), ciclopirox (gel), clotrimazole/betamethasone lotion, clotrimazole Rx (cream, solution), econazole, Ertacoz, Exelderm, Extina, ketoconazole, Lamisil AT (spray), Lotrisone, Luzu, Mentax, naftifine, Naftin, nystatin/triamcinolone, oxiconazole, Oxistat, Vusion

Passed Unanimously

Approved as Recommended

### Anti-Infectives – Topical

**Preferred:** BenzaClin (pump, gel), clindamycin (solution), erythromycin (solution)

**Non-Preferred:** 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

Passed Unanimously

Approved as Recommended

### Glucagon-like Peptide –1 (GLP-1) Agents

**Preferred:** Bydureon, Byetta, Victoza

**Non-Preferred:** Adlyxin, Soliqua, Tanzeum, Trulicity, Xultophy

Passed Unanimously

Approved as Recommended

### Insulin – Long Acting

**Preferred:** Lantus, Levemir

**Non-Preferred:** Basaglar, Toujeo, Tresiba

Passed Unanimously

Approved as Recommended
<table>
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<tr>
<th>Sodium Glucose Co-Transporter 2 (SGLT-2) Inhibitors</th>
<th>Audio Cast Time 2:43:42</th>
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<tbody>
<tr>
<td><strong>Preferred</strong>: Farxiga, Invokana</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td><strong>Non-Preferred</strong>: Invokamet, Invokamet XR, Jardiance, Synjardy, Xigduo XR</td>
<td>Passed Unanimously</td>
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<tr>
<th>Anticoagulants – Oral</th>
<th>Audio Cast Time 2:44:08</th>
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<tbody>
<tr>
<td><strong>Preferred</strong>: Coumadin, Eliquis, Jantoven, Pradaxa, warfarin, Xarelto</td>
<td>Approved as Recommended</td>
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<tr>
<td><strong>Non-Preferred</strong>: Savaysa, Xarelto (dose pak)</td>
<td>Passed Unanimously</td>
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<tr>
<th>Platelet Inhibitors</th>
<th>Audio Cast Time 2:44:32</th>
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<tbody>
<tr>
<td><strong>Preferred</strong>: Aggrenox, Brilinta, clopidogrel, dipyridamole</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td><strong>Non-Preferred</strong>: dipyridamole/aspirin, Durlaza, Effient, Plavix, ticlopidine, Yosprala, Zontivity</td>
<td>Passed Unanimously</td>
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<tr>
<th>Epinephrine, Self-injected</th>
<th>Audio Cast Time 2:45:01</th>
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<tr>
<td><strong>Preferred</strong>: epinephrine pen 0.3mg (generic Epi-pen), epinephrine pen 0.15mg (generic Epi-pen Jr.)</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td><strong>Non-Preferred</strong>: Adrenaclick, EpiPen, EpiPen Jr., epinephrine pen (generic Adrenaclick)</td>
<td>Passed Unanimously</td>
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<tr>
<th>Non-Steroidal Anti-inflammatory Drugs (NSAIDS) – Ophthalmic</th>
<th>Audio Cast Time 2:45:33</th>
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<tr>
<td><strong>Preferred</strong>: diclofenac, flurbiprofen, ketorolac/ketorolac LS, Ilevro</td>
<td>Approved as Recommended</td>
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<tr>
<td><strong>Non-Preferred</strong>: Acular, Acular LS, Acuvail, bromfenac, BromSite, Nevanac, Ocuflon, Prolensa</td>
<td>Passed Unanimously</td>
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<tr>
<td><strong>Fluoroquinolones – Otic</strong></td>
<td><strong>Preferred:</strong> Cipro HC, Ciprodex, ciprofloxacin</td>
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<tr>
<th><strong>Phosphate Binders/Regulators</strong></th>
<th><strong>Preferred:</strong> calcium acetate, Eliphos, Fosrenol, Renagel</th>
<th><strong>Non-Preferred:</strong> Auryxia, Phoslyra, Renvela, Velphoro</th>
<th><strong>Passed Unanimously</strong></th>
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<tr>
<th><strong>Anticholinergics/COPD Agents</strong></th>
<th><strong>Preferred:</strong> Atrovent HFA, Combivent Respimat, ipratropium, ipratropium/albuterol, Spiriva, Stiolto Respimat</th>
<th><strong>Non-Preferred:</strong> Anoro Ellipta, Bevespi Aerosphere, Daliresp, Incruse Ellipta, Seebri Neohaler, Spiriva Respimat, Tudorza Pressair, Utibron Neohaler</th>
<th><strong>Passed Unanimously</strong></th>
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<tr>
<th><strong>Corticosteroid/Beta-2 Adrenergic Agent (Long Acting) Combinations – Inhaled</strong></th>
<th><strong>Preferred:</strong> Advair Diskus, Dulera, Symbicort</th>
<th><strong>Non-Preferred:</strong> Advair HFA, Breo Ellipta</th>
<th><strong>11 in favor, 1 opposed, 0 abstentions</strong></th>
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<tr>
<th><strong>Corticosteroids – Intranasal</strong></th>
<th><strong>Preferred:</strong> fluticasone</th>
<th><strong>Non-Preferred:</strong> Beconase AQ*, budesonide, Dymista, flunisolide, mometasone, Nasonex, Omnaris, QNASL*, Veramyst, Zetonna</th>
<th><strong>Passed Unanimously</strong></th>
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*Beclomethasone automated prior authorization bypass for patients with established HIV/AIDS diagnosis or indicative treatment.
G. Final Comments and Adjournment

Janet Zachary-Elkind, Deputy Director

Anthony Merola, RPh, MBA
Contact for post meeting questions: 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.