New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for April 27, 2016

The Medicaid DUR Board met on Wednesday, April 27, 2016 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 - 02:21)

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 Members
Lisa Anzisi, PharmD
Leigh Briscoe-Dwyer, PharmD
Donna Chiefari, PharmD
Marla Eglowstein, MD
James Hopsicker, RPh, MBA
Renante Ignacio, MD

Jadwiga Najib, PharmD
Paula Panzer, MD
Asa Radix, MD
Michelle Rainka, PharmD
James Saperstone, MD
John Wikiera

Magellan Medicaid Administration
Carole Kerzic, RPh

State University at Buffalo
Barbara Rogler, PharmD, MS

B. Public Comment Period

(Audio Cast Time 02:21 - 01:31:32)

The following speakers provided public comment to the Board:

1. Paul Wacnik, PhD Pfizer Inc Opioids – Long-Acting
2. Deven Shah, RPh, MBA Purdue Pharma L.P. Opioids – Long-Acting
3. Vera Antonios, MD Harlem United HCV–Direct Acting Antivirals
4. Reed Vreeland, Housing Works HCV–Direct Acting Antivirals
5. Belkys Garcia, Esq., The Legal Aid Society HCV–Direct Acting Antivirals
6. Samantha Paz, BOOM!Health HCV–Direct Acting Antivirals
7. Elizabeth Owens, VocalNY HCV–Direct Acting Antivirals
8. Michele Starr, VocalNY HCV–Direct Acting Antivirals
9. Kaysie Horwedel, VocalNY HCV–Direct Acting Antivirals
10. Anantha Ramani, MD, Mountain View Medical Practice HCV–Direct Acting Antivirals
11. Helen Adams, RPA-C, Riverdale Gastroenterology HCV–Direct Acting Antivirals
12. James Spellman, Gilead HCV–Direct Acting Antivirals
14. Lindsay Hermony, PharmD, Merck & Co., Inc HCV–Direct Acting Antivirals
15. Sunny Kumar, PharmD, Bristol-Myers Squibb HCV–Direct Acting Antivirals
16. Richard Jackson, Vocal NY HCV–Direct Acting Antivirals
17. John Richter, MHANYS Antipsychotics – Second Generation
18. David Pallas, MD, Albany Cty Mental Health Clinic Antipsychotics – Second Generation
19. Francis S Lobo, BS, MS, PhD, Sunovion Antipsychotics – Second Generation
20. Laura Bartels, PharmD, MML, Otsuka America Pharm., Inc Antipsychotics – Second Generation
21. Laura Bartels, PharmD, MML, Otsuka America Pharm., Inc Antipsychotics, Injectable
22. Timothy Birner, PharmD, MBA, Alkermes, Inc. Antipsychotics, Injectable
23. Shaffee Bacchus, Pharm.D, Janssen Scientific Affairs, Inc Antipsychotics, Injectable
24. Gerard Buonpane, PharmD, Tris Pharma CNS Stimulants
25. Donna Palumbo, PhD, Pfizer Inc. CNS Stimulants
26. Alan Chant, Sanofi US Insulin – Long-Acting
27. Jeffrey Joseph, MD, Novo Nordisk Inc. Insulin – Long-Acting
28. Beth D’Ambrosio, PharmD, Novartis Pharmaceuticals Corp. Anticholinergics - COPD Agents
29. Rocco A. Zullo, PharmD, GSK Anticholinergics - COPD Agents
30. Lily Chan, PharmD, Sunovion Beta-2 Adrenergic Agents - Inhaled LA

C. Preferred Drug Program Clinical Reviews

Carole Kerzic, RPh
Robert Correia, PharmD

1. Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) – Prescription
   - New products - Tivorbex (indomethacin), Vivlodex (meloxicam)
   - No new clinical information

2. Opioid Antagonists
   - New product - Narcan (naloxone nasal spray)
• Practice guidelines

3. Opioids - Long Acting
   • New product - Belbuca (buprenorphine) buccal film
   • Expanded indications- Oxycontin (oxycodone)
   • FDA communications- (Conzip, Ultram ER)
   • Guidelines

4. Hepatitis C Agents – Direct Acting Antivirals (DAAs)
   • New products - Daklinza (daclatasvir), Technivie (ombitasvir/ paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)
   • Update on the Management of Chronic Hepatitis-C Infection
   • Product guidelines
   • Clinical Trials
   • Therapy considerations

   In addition, Dr. Rogler presented updates to clinical information and drug utilization associated with the DAA agents in the management of chronic hepatitis C. The information included data associated with lab testing, DAA drug utilization, duration of therapy and adherence.

5. Antipsychotics – Second Generation
   • New product - Vraylar (cariprazine)
   • FDA communications- Clozapine (Fazaclo, Versacloz)
   • Key label revisions - Risperdal (risperidone), Fanapt (iloperidone)

6. Antipsychotics, Injectable (Initial class review)
   • Background
   • Practice guidelines
   • Label information
   • Place in therapy

7. Central Nervous System (CNS) Stimulants
   • New products - Aptensio XR (methylphenidate extended-release), Quillichew ER (methylphenidate extended-release), Dyanavel XR (amphetamine oral suspension)
   • FDA communication- Daytrana (methylphenidate transdermal system)
   • Label revisions

8. Selective Serotonin Reuptake Inhibitors (SSRIs)
   • No new clinical information
9. Acne Agents - Prescription, Topical
   • Background
   • Label information
   • Place in therapy

10. Antibiotics – Topical
    • No new clinical information

11. Insulin – Long-Acting
    • New products - Toujeo 300 U/mL (insulin glargine), Tresiba (insulin degludec)
    • FDA communication
    • Practice guidelines- American Diabetes Association (ADA) Standards of Medical Care in Diabetes – Two updates

12. Fluoroquinolones – Otic
    • No new clinical information

13. Anticholinergics - COPD Agents
    • New products- Stiolto Respimat (tiotropium/olodaterol), Seebri Neohaler (glycopyrrolate), Utibron Neohaler (indacaterol/glycopyrrolate)
    • New indication- Spiriva Respimat (tiotropium)
    • Practice guidelines- Global Initiative for Asthma (GINA) - Global Strategy for Asthma Management and Prevention - 2015
    • Label revision- Tudorza Pressair® (aclidinium bromide)

    • No new clinical information

    • No new clinical information

E. Executive Session

The Board recessed the public session at 1:45 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 3:15 pm.
F. DUR Board Recommendations

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

<table>
<thead>
<tr>
<th>Recommendations of DUR Board</th>
<th>Commissioner's Final Determination</th>
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</thead>
<tbody>
<tr>
<td><strong>Prescription Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)</strong></td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td><strong>Preferred</strong></td>
<td>Passed Unanimously</td>
</tr>
<tr>
<td>diclofenac sodium XR, Ibuprofen, indomethacin, ketorolac, meloxicam tablet, naproxen, naproxen EC, piroxicam, sulindac, Voltaren Gel</td>
<td></td>
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<tr>
<td><strong>Non-preferred</strong></td>
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<tr>
<td>Anaprox DS, Arthrotec, Cambia, Celebrex, celecoxib, Daypro, diclofenac potassium, diclofenac sodium, diclofenac topical gel, diclofenac topical solution, diclofenac/misoprostol, diflunisal, Duexis, etodolac, etodolac ER, Feldene, fenoprofen, Flector patch, flurbiprofen, Indocin, indomethacin SR, ketoprofen, ketoprofen SA, meclofenamate, mfenamic acid, meloxicam suspension, Mobic, nabumetone, Nalfon, Naprelan, Naprosyn, Naprosyn EC, naproxen CR, naproxen sodium, oxaprozin, Pennsaid, Ponstel, Sprix, Tivorbex, tolmetin, Vimovo, Vivlodex, Voltaren XR, Zipsor, Zorvolex</td>
<td></td>
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<tr>
<td><strong>Opioid Antagonists</strong></td>
<td>Approved as Recommended</td>
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<tr>
<td><strong>Preferred</strong></td>
<td>Passed Unanimously</td>
</tr>
<tr>
<td>naloxone (syringe, vial), naltrexone, Narcan (Nasal Spray), ReVia</td>
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<tr>
<td><strong>Non-preferred</strong></td>
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### Opioids – Long Acting

**Preferred**
- Butrans*, fentanyl transdermal 12, 25, 50, 75, 100 mcg, morphine SR tablet

*The DUR Board voted (11 in favor, 1 opposed, 1 abstention) to alter the DoH recommendation and move Butrans to preferred status.

**Non-preferred**
- Avinza, Belbuca, Conzip, Duragesic, Embeda ER, Exalgo, fentanyl transdermal 37.5, 62.5, 87.5 mcg., hydromorphone ER, Hysingla ER, Kadian, MS Contin, morphine sulfate ER capsule (generic Avinza), morphine sulfate ER capsule (generic Kadian), Nucynta ER, Opana ER, oxycodone ER, Oxycontin, oxymorphone ER, tramadol ER, Ultram ER, Zohydro ER

Passed Unanimously

### Hepatitis C Agents- Direct Acting Antivirals

**Preferred**
- Daklinza, Harvoni, ribavirin, Sovaldi, Technivie, Viekira Pak, Zepatier

**Non-preferred**
- Copegus, Moderiba, Olysio, Rebetol, Ribapak, Ribosphere

Passed: 12 in favor, 0 opposed, 1 abstention

### HCV DAA clinical criteria

Remove the disease prognosis and severity clinical criteria for non-preferred products.

Passed: 12 in favor, 0 opposed 1 abstention
### Antipsychotics – Second Generation

**Preferred**
- Abilify, clozapine, Fanapt, Latuda, olanzapine tablet, quetiapine, risperidone, Saphris, Seroquel XR, ziprasidone

**Non-preferred**
- aripiprazole, aripiprazole ODT, clozapine ODT, Clozaril, FazaClo, Geodon, Invega, olanzapine ODT, paliperidone ER, Rexulti, Risperdal, Seroquel, Versacloz, Vraylar, Zyprexa

Passed Unanimously

Approved as Recommended

### Antipsychotics – Injectable

**Preferred**
- Abilify Maintena, Aristada, fluphenazine decanoate, Haldol decanoate, haloperidol decanoate, Invega Sustenna, Invega Trinza, Risperdal Consta, Zyprexa Relprevv

**Non-preferred**
- None

Passed Unanimously

Approved as Recommended

### Central Nervous System Stimulants

**Preferred**
- Adderall, Adderall XR, amphetamine salt combo IR, Daytrana, dexamphetamine, dextroamphetamine tablet, Focalin XR, Metadate ER, Methylin, methylphenidate tablet, methylphenidate ER (Concerta), methylphenidate SR (10 and 20 mg tablet), Quillivant XR, Vyvanse

**Non-preferred**
- amphetamine salt combo ER, Aptensio XR, Concerta, Desoxyn, Dexedrine, dexamphetamine ER (generic Focalin XR), dextroamphetamine ER, dextroamphetamine solution, Dyanavel XR, Evekeo, Focalin, Metadate CD, methamphetamine, methylphenidate CD (Metadate CD), methylphenidate ER (Ritalin LA), methylphenidate (chewable tablet, solution), modafinil, Nuvigil, Procentra, Provigil, Quillichew ER, Ritalin, Ritalin LA, Zenzedi

Passed Unanimously

Approved as Recommended
### Selective Serotonin Reuptake Inhibitors (SSRIs)

**Preferred**
citalopram, escitalopram tablet, fluoxetine capsule, fluoxetine solution, paroxetine, sertraline

**Non-preferred**
Brintellix, Brisdelle, Celexa, escitalopram solution, fluoxetine tablet (10 mg, 20 mg), fluoxetine 60mg, fluoxetine DR weekly, fluvoxamine, fluvoxamine ER, Lexapro, paroxetine CR, Paxil, Paxil CR, Pexeva, Prozac, Sarafem, Viibryd, Zoloft

Passed Unanimously

**Approved as Recommended**

### Acne Agents – Prescription, Topical

**Preferred**
Differin, Retin-A (cream, gel), Tazorac

**Non-preferred**
Aczone, adapalene, Atralin, Avita, Azelex, Epiduo, Fabior Retin-A micro, tretinoin, tretinoin micro, Veltin, Ziana

Passed Unanimously

**Approved as Recommended**

### Antibiotics – Topical

**Preferred**
mupirocin ointment

**Non-preferred**
Altabax, Bactroban (cream, ointment), Bactroban Nasal (ointment), Centany (ointment), mupirocin cream

Passed Unanimously

**Approved as Recommended**

### Insulin – Long Acting

**Preferred**
Lantus, Levemir

**Non-preferred**
Toujeo, Tresiba

Passed Unanimously

**Approved as Recommended**
<table>
<thead>
<tr>
<th>Category</th>
<th>Drug List</th>
<th>Issue</th>
<th>Approval Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fluoroquinolones - Otic</strong></td>
<td>Cipro HC, Ciprodex, Ciprofloxacin (*), Ciprobay</td>
<td>The DUR Board voted (unanimously) to alter the DoH recommendation and move ciprofloxacin to preferred status.</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td><strong>Anticholinergics - COPD Agents</strong></td>
<td>Atrovent HFA, Combivent Respimat, Ipratropium, Ipratropium/ipratropium/albuterol/Spiriva</td>
<td>Passed Unanimously</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td><strong>Antihistamines - Second Generation</strong></td>
<td>Cetirizine OTC (1 mg/ml), fexofenadine OTC suspension, levocetirizine tablet, loratadine OTC (ODT, solution, tablet)</td>
<td>Passed Unanimously</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td><strong>Beta-2 Adrenergic Agents- Long Acting</strong></td>
<td>Foradil, Perforomist, Serevent</td>
<td>Passed Unanimously</td>
<td>Approved as Recommended</td>
</tr>
</tbody>
</table>
G. Final Comments and Adjournment

Janet Zachary-Elkind
Announced resignations of Board Members Jeffrey Dubitsky, RPh and William Scheer, RPh and thanked them for their service.

Anthony Merola, RPh, MBA
Contact for post meeting questions: DUR@health.ny.gov or 518-486-3209

Meeting adjourned at 3:45 PM

H. Commissioner 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 $8.9M. The savings are achieved through changes in utilization to equally effective and less expensive products including the receipt of supplemental rebates from pharmaceutical manufacturers.