

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
13.	Jodi Walker, PharmD, BCPS	Abbvie	HCV–Direct Acting Antivirals
14.	Lindsay Hermany, 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

(Audio Cast Time 1:32:45 - 4:17:05)

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)

(Audio Cast Time 1:35:12)

- Practice guidelines

3. Opioids - Long Acting

(Audio Cast Time 1:44:12)

- New product - Belbuca (buprenorphine) buccal film
- Expanded indications- Oxycontin (oxycodone)
- FDA communications- (Conzip, Ultram ER)
- Guidelines

4. Hepatitis C Agents – Direct Acting Antivirals (DAAs)

(Audio Cast Time 1:55:02)

- 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

(Audio Cast Time 3:21:00)

- New product - Vraylar (cariprazine)
- FDA communications- Clozapine (Fazaclo, Versacloz)
- Key label revisions - Risperdal (risperidone), Fanapt (iloperidone)

6. Antipsychotics, Injectable (Initial class review)

(Audio Cast Time 3:29:00)

- Background
- Practice guidelines
- Label information
- Place in therapy

7. Central Nervous System (CNS) Stimulants

(Audio Cast Time 3:39:11)

- 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

(Audio Cast Time 3:53:41)

- Background
- Label information
- Place in therapy

10. Antibiotics – Topical

- No new clinical information

11. Insulin – Long-Acting

(Audio Cast Time 4:00:14)

- 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

(Audio Cast Time 4:09:45)

- 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)

14. Antihistamines – Second Generation

- No new clinical information

15. Beta-2 Adrenergic Agents – Inhaled Long Acting

- No new clinical information

E. Executive Session

(Recess to Excessive Session - Audio Cast Time 4:17:55)

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

(Audio Cast Time 4:18:08 – 4:35:45)

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

Recommendations of DUR Board	Commissioner's Final Determination
<p>Prescription Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) <small>Audio Cast Time - 4:21:10</small></p> <p>Preferred diclofenac sodium XR, Ibuprofen, indomethacin, ketorolac, meloxicam tablet, naproxen, naproxen EC, piroxicam, sulindac, Voltaren Gel</p> <p>Non-preferred 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, mefenamic 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</p> <p style="text-align: right;">Passed Unanimously</p>	<p style="text-align: center;">Approved as Recommended</p>
<p>Opioid Antagonists <small>Audio Cast Time - 4:24:35</small></p> <p>Preferred naloxone (syringe, vial), naltrexone, Narcan (Nasal Spray), ReVia</p> <p>Non-preferred Evzio</p> <p style="text-align: right;">Passed Unanimously</p>	<p style="text-align: center;">Approved as Recommended</p>

<p>Opioids – Long Acting Audio Cast Time - 4:25:05</p> <p>Preferred Butrans*, fentanyl transdermal 12, 25, 50, 75, 100 mcg, morphine SR tablet</p> <p>*The DUR Board voted (11 in favor, 1 opposed, 1 abstention) to alter the DoH recommendation and move Butrans to preferred status.</p> <p>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</p> <p style="text-align: right;">Passed Unanimously</p>	<p style="text-align: center;">Approved as Recommended</p>
<p>Hepatitis C Agents- Direct Acting Antivirals Audio Cast Time - 4:27:12</p> <p>Preferred Daklinza, Harvoni, ribavirin, Sovaldi, Technivie, Viekira Pak, Zepatier</p> <p>Non-preferred Copegus, Moderiba, Olysio, Rebetol, Ribapak, Ribasphere</p> <p style="text-align: center;">Passed: 12 in favor, 0 opposed, 1 abstention</p>	<p style="text-align: center;">Approved as Recommended</p>
<p>HCV DAA clinical criteria Audio Cast Time - 4:28:25</p> <p>Remove the disease prognosis and severity clinical criteria for non-preferred products.</p> <p style="text-align: center;">Passed: 12 in favor, 0 opposed 1 abstention</p>	<p style="text-align: center;">Approved as Recommended</p>

<p>Antipsychotics – Second Generation Audio Cast Time - 4:29:20</p> <p>Preferred Abilify, clozapine, Fanapt, Latuda, olanzapine tablet, quetiapine, risperidone, Saphris, Seroquel XR, ziprasidone</p> <p>Non-preferred aripiprazole, aripiprazole ODT, clozapine ODT, Clozaril, FazaClo, Geodon, Invega, olanzapine ODT, paliperidone ER, Rexulti, Risperdal, Seroquel, Versacloz, Vraylar, Zyprexa</p> <p style="text-align: right;">Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Antipsychotics – Injectable Audio Cast Time - 4:29:57</p> <p>Preferred Abilify Maintena, Aristada, fluphenazine decanoate, Haldol decanoate, haloperidol decanoate, Invega Sustenna, Invega Trinza, Risperdal Consta, Zyprexa Relprev</p> <p>Non-preferred None</p> <p style="text-align: right;">Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Central Nervous System Stimulants Audio Cast Time - 4:30:19</p> <p>Preferred Adderall, Adderall XR, amphetamine salt combo IR, Daytrana, dexamethylphenidate, dextroamphetamine tablet, Focalin XR, Metadate ER, Methylin, methylphenidate tablet, methylphenidate ER (<i>Concerta</i>), methylphenidate SR (10 and 20 mg tablet), Quillivant XR, Vyvanse</p> <p>Non-preferred amphetamine salt combo ER, Aptensio XR, Concerta, Desoxyn, Dexedrine, dexamethylphenidate ER (generic Focalin XR), dextroamphetamine ER, dextroamphetamine solution, Dyanavel XR, Evekeo, Focalin, Metadate CD, methamphetamine, methylphenidate CD (<i>Metadate CD</i>), methylphenidate ER (<i>Ritalin LA</i>), methylphenidate (chewable tablet, solution), modafinil, Nuvigil, Procentra, Provigil, Quillichew ER, Ritalin, Ritalin LA, Zenedi</p> <p style="text-align: right;">Passed Unanimously</p>	<p>Approved as Recommended</p>

<p>Selective Serotonin Reuptake Inhibitors (SSRIs) Audio Cast Time - 4:31:00</p> <p>Preferred citalopram, escitalopram tablet, fluoxetine capsule, fluoxetine solution, paroxetine, sertraline</p> <p>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</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Acne Agents – Prescription, Topical Audio Cast Time - 4:31:28</p> <p>Preferred Differin, Retin-A (cream, gel), Tazorac</p> <p>Non-preferred Aczone, adapalene, Atralin, Avita, Azelex, Epiduo, Fabior Retin-A micro, tretinoin, tretinoin micro, Veltin, Ziana</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Antibiotics – Topical Audio Cast Time - 4:32:11</p> <p>Preferred mupirocin ointment</p> <p>Non-preferred Altabax, Bactroban (cream, ointment), Bactroban Nasal (ointment), Centany (ointment), mupirocin cream</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Insulin – Long Acting Audio Cast Time - 4:32:38</p> <p>Preferred Lantus, Levemir</p> <p>Non-preferred Toujeo, Tresiba</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>

<p>Fluoroquinolones - Otic</p> <p>Preferred Ciprodex, ciprofloxacin*, Cipro HC</p> <p>*The DUR Board voted (unanimously) to alter the DoH recommendation and move ciprofloxacin to preferred status.</p> <p>Non-preferred ofloxacin</p>	<p>Audio Cast Time - 4:33:00</p>	<p>Approved as Recommended</p>
<p>Anticholinergics - COPD Agents</p> <p>Preferred Atrovent HFA, Combivent Respimat, ipratropium, ipratropium/albuterol, Spiriva</p> <p>Non-preferred Anoro Ellipta, Daliresp, Incruse Ellipta, Seebri Neohaler, Spiriva Respimat, Stiolto Respimat, Tudorza Pressair, Utibron Neohaler</p>	<p>Audio Cast Time - 4:34:25</p>	<p>Approved as Recommended</p>
<p>Antihistamines - Second Generation</p> <p>Preferred cetirizine OTC (1 mg/ml), fexofenadine OTC suspension, levocetirizine tablet, loratadine OTC (ODT, solution, tablet)</p> <p>Non-preferred cetirizine OTC (tablet, chewable, syrup/solution 5 mg/ml), cetirizine-D OTC, Clarinex, Clarinex-D OTC, desloratadine, fexofenadine OTC tablet, levocetirizine solution, loratadine-D OTC, Semprex-D, Xyzal</p>	<p>Audio Cast Time - 4:34:50</p>	<p>Approved as Recommended</p>
<p>Beta-2 Adrenergic Agents- Long Acting</p> <p>Preferred Foradil, Perforomist, Serevent</p> <p>Non-preferred Arcapta, Brovana, Striverdi Respimat</p>	<p>Audio Cast Time - 4:35:16</p>	<p>Approved as Recommended</p>

G. Final Comments and Adjournment

Audio Cast Time (4:35:50 – 4:39:50)

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.