New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for September 18, 2014

The Medicaid DUR Board met on Thursday, September 18, 2014 from 9:00 AM to 4:00 PM
Meeting Room 3, 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

(Product of Health
Janet Zachary-Elkind
Robert Correia, PharmD
Anthony Merola, RPh, MBA

DUR Board
Lisa Anzisi, PharmD
Nancy Balkon, PhD, NP
Donna Chiefari, PharmD
Jeffrey Dubitsky, RPh
Renante Ignacio, MD

SUNY – University at Buffalo Staff
Barbara Rogler, PharmD, MS
Linda Catanzaro, PharmD

AIDS Institute
Charles Gonzalez, MD

Magellan Medicaid Administration
Eileen Zimmer, PharmD, MBA

(Audio Cast Time 00:01 – 07:00)
B. Public Comment Period

(Audio Cast Time 07:02 - 58:25)

The following speakers provided public comment to the DUR Board:

1. Scott S. Brehaut, MD  Private Practice  Anticoagulants - oral
2. Arsalan Khan, PharmD, MBA  Janssen Scientific Affairs  Anticoagulants - oral
3. Henry Tan, MD  Private Practice  Anticoagulants - oral
4. Shallini Hede, PharmD  BMS  Anticoagulants - oral
5. Maria Dugandzic, PharmD  Boehringer Ingelheim Pharm  Anticoagulants - oral
6. Deva McGriff  Bayer HealthCare Pharm  Oral Agents for PAH
7. Bhavisha Sheth, PharmD  United Therapeutics  Oral Agents for PAH
8. Erin Paul, PhD  Actelion Pharmaceuticals  Oral Agents for PAH
9. William Mullen, PA-C, MPH  RB Pharmaceuticals  Agents for Opioid Dependence
10. Gay Owens, PharmD  Kaleo, Inc.  Opioid Antagonists
11. Dawn Dluge-Aungst, RPA-C  Private Practice  SGLT2 Inhibitors
12. Andrea Traina, PharmD  AstraZeneca Pharmaceuticals  SGLT2 Inhibitors
13. Arsalan Khan, PharmD, MBA  Janssen Scientific Affairs  SGLT2 Inhibitors
14. Arsalan Khan, PharmD, MBA  Janssen Scientific Affairs  Hepatitis-C Virus
15. Jeffrey Olson, PharmD  Gilead  Hepatitis-C Virus
16. Jules Levin  NATAP  Hepatitis-C Virus

C. Preferred Drug Program Clinical Reviews

(Audio Cast Time 58:06 – 2:12:36)

Eileen Zimmer, PharmD
Robert Correia, PharmD

1. AntiCoagulants – oral  (Audio Cast Time 58:25)
2. Oral Agents for Pulmonary Arterial Hypertension  (Audio Cast Time 1:10:14)
3. Agents for Opioid Dependence  (Audio Cast Time 1:27:55)
4. Opioid Antagonists  (Audio Cast Time 1:36:55)
5. Sodium Glucose co-transporter 2 Inhibitors  (Audio Cast Time 1:47:00)
6. Alpha-Glucosidase Inhibitors  (Audio Cast Time 2:01:50)
7. Meglitinides  (Audio Cast Time 2:04:50)

D. Executive Session

The Board recessed the public session at 11:30 A.M. 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 1:00 pm.
E. DUR Board PDP Recommendations

Based on the clinical and financial information, the Board unanimously (unless otherwise noted) recommended the following to the Commissioner of Health for final determination:

<table>
<thead>
<tr>
<th>Recommendations of the DUR Board</th>
<th>Commissioner's Final Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anticoagulants – oral</strong></td>
<td>2:13:56</td>
</tr>
<tr>
<td>Preferred</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td>Coumadin, Eliquis, Jantoven, Pradaxa, warfarin</td>
<td></td>
</tr>
<tr>
<td>Non-preferred</td>
<td></td>
</tr>
<tr>
<td>Xarelto</td>
<td></td>
</tr>
<tr>
<td><strong>Oral Agents for Pulmonary Arterial Hypertension (PAH)</strong></td>
<td>2:15:29</td>
</tr>
<tr>
<td>Preferred</td>
<td>Approved as Recommended</td>
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<tr>
<td>Letairis, Tracleer</td>
<td></td>
</tr>
<tr>
<td>Non-preferred</td>
<td></td>
</tr>
<tr>
<td>Adempas, Opsumit, Orenitram</td>
<td></td>
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<tr>
<td><strong>Agents for Opioid Dependence</strong></td>
<td>2:16:41</td>
</tr>
<tr>
<td>Preferred</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td>buprenorphine, Suboxone Film</td>
<td></td>
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<tr>
<td>Non-preferred</td>
<td></td>
</tr>
<tr>
<td>buprenorphine/naloxone tablet, Zubsolv</td>
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<tr>
<td>Vote: 9 support, 1 oppose</td>
<td></td>
</tr>
<tr>
<td><strong>Opioid Antagonists</strong></td>
<td>2:17:37</td>
</tr>
<tr>
<td>Preferred</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td>naloxone syringe, naloxone vial, naltrexone, ReVia</td>
<td></td>
</tr>
<tr>
<td>Non-preferred</td>
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<tr>
<td>Evzio</td>
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<tr>
<td><strong>Sodium Glucose co-transporter 2 (SGLT2) Inhibitors</strong></td>
<td>2:18:45</td>
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<tr>
<td>Preferred</td>
<td>Approved as Recommended</td>
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<tr>
<td>Invokana</td>
<td></td>
</tr>
<tr>
<td>Non-preferred</td>
<td></td>
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<tr>
<td>Farxiga, Jardiance</td>
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</table>
F. Drug Utilization Reviews  

1. Hepatitis C Virus – Clinical Criteria Review  
   (Audio Cast Time 2:20:36 - 3:20:15)  
   (pegylated interferon, ribavirin, boceprevir, simeprevir, sofosbuvir, telaprevir)  

   Drs. Linda Catanzaro and Barbara Rogler presented a review of Hepatitis C Virus (HCV) Agents including an update of place in therapy with particular focus on the most recent drug to market, sofosbuvir. Current treatment guidance based on expert national and international opinion were detailed, and the Board was charged with evaluation of this detailed information. Discussion included physician evaluation of disease, patient eligibility for treatment, and the financial impact of therapy.

   The DUR Board recommended the following:

   **Hepatitis C Virus – Clinical Criteria Review**  
   (vote 3:17:40–3:18:58)  
   (pegylated interferon, ribavirin, boceprevir, simeprevir, sofosbuvir, telaprevir)  

   Implement clinical criteria and/or point of service editing addressing:
   
   - FDA labeling and compendia supported use
   - Prescriber experience and training
   - Patient readiness and adherence
   - Disease Prognosis and Severity

   Passed Unanimously


   Dr. Irene Hong presented a review of Memantine ER (Namenda XR) utilization. The review considered the FDA-approved indication of treatment of moderate-to-severe dementia of the Alzheimer’s type and the Compendia supported use of dementia. Board discussion included the potential for off-label use of the medication and concerns regarding side effects when the drug is prescribed for the elderly population. The Board also considered the impending discontinuation of
the immediate-release form of the medication from the open market, the anticipated movement of patient therapy to the newly released time-release formulation, and the consideration of future generic formulations.

The DUR Board recommended the following:

**Memantine ER (Namenda XR) – Clinical/Utilization Review**

Confirm diagnosis for the FDA-approved indication:
- Dementia or Alzheimer’s Disease

Absence of covered diagnosis in patient’s claim history will require prescriber involvement.

Passed Unanimously

**Memantine ER (Namenda XR) – Clinical/Utilization Review**

Step Therapy: Trial with memantine immediate-release

Override will require prescriber involvement.

Passed Unanimously

3. Tetrabenazine (Xenazine) - Clinical/Utilization Review  

Dr. Holly Coe presented a review of tetrabenazine (Xenazine). The review considered the FDA-approved indication of treatment of chorea in patients with Huntington’s disease, and the compendia supported uses of Gilles de la Tourette's syndrome and tardive dyskinesia. Discussion included consideration of the risks of suicidality and depression when using this medication when weighed against the possible benefits of treatment. Use in pregnancy was also discussed.

The DUR Board recommended the following:

**Tetrabenazine (Xenazine) – Clinical/Utilization Review**

Confirm diagnosis for the FDA and Compendia approved indications in patients ≥ 18 years:
- Chorea associated with Huntington’s disease
- Gilles de la Tourette's syndrome
- Tardive dyskinesia

Absence of covered diagnosis in patient’s claim history will require prescriber involvement.

Passed Unanimously

**Tetrabenazine (Xenazine) – Clinical/Utilization Review**

Educational intervention at the prescriber level highlighting safety issues regarding depression and suicidality and reinforcing prescribing for covered uses only.

Passed Unanimously
4. Tasimelteon (Hetlioz) - Clinical/Utilization Review

Dr. Holly Coe presented a review of tasimelteon (Hetlioz™). The review considered the FDA-approved indication of Non-24-hour sleep-wake disorder (Non-24) in patients who are totally blind. While tasimelteon is currently the only FDA-approved agent for this condition, the review considered the American Academy of Sleep Medicine (AASM) assertion that doses of melatonin may entrain blind patients with Non-24. Discussion also included the necessity of accurate diagnosis of the condition by prescribers and the risk/benefit ratio of this medication considering the potential side effects in the elderly, as well as pregnant patients and those with hepatic impairment.

The DUR Board recommended the following:

<table>
<thead>
<tr>
<th>Tasimelteon (Hetlioz) – Clinical/Utilization Review</th>
<th>(vote 4:51:50 - 5:12:28)</th>
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<tbody>
<tr>
<td>Confirm diagnosis for the FDA-approved indication:</td>
<td></td>
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<tr>
<td>Non-24-hour sleep-wake disorder in totally blind patients only</td>
<td></td>
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<tr>
<td>Absence of covered diagnosis in patient’s claim history will require prescriber involvement</td>
<td></td>
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<tr>
<td>Vote: 6 support, 3 oppose</td>
<td></td>
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<tbody>
<tr>
<td>Quantity Limit:</td>
<td></td>
</tr>
<tr>
<td>1 unit per day (30 units per 30 days)</td>
<td></td>
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<tr>
<td>Vote: 6 support, 1 oppose, 2 abstentions</td>
<td></td>
</tr>
</tbody>
</table>

G. Final Comments and Adjournment

Janet Zachary-Elkind

Meeting adjourned at 4:00 PM

F. Commissioner Final Determinations

The impact of the final determinations on the PDP is as follows:

State Public Health Population:
- Minimal effect on Medicaid enrollees, as a large majority of enrollees 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:
  o Annual gross savings associated with these therapeutic classes under the PDP are estimated at $1.9M. The savings are achieved through changes in utilization to equally effective and less expensive products including the receipt of supplemental rebates from pharmaceutical manufacturers.