

**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

(Audio Cast Time 00:01 – 07:00)

Department of Health

Janet Zachary-Elkind
Robert Correia, PharmD
Anthony Merola, RPh, MBA

John Naioti, RPh
Robert Sheehan, RPh
Monica Toohey, RPh

DUR Board

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

Jadwiga Najib, PharmD
John Noviasky, PharmD
James Saperstone, MD
John Wikiera

SUNY – University at Buffalo Staff

Barbara Rogler, PharmD, MS
Linda Catanzaro, PharmD

Holly Coe, PharmD
Irene Hong, PharmD

AIDS Institute

Charles Gonzalez, MD

Magellan Medicaid Administration

Eileen Zimmer, PharmD, MBA

B. Public Comment Period

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

The following speakers provided public comment to the DUR Board:

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|-----|---------------------------|-----------------------------|------------------------------|
| 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

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| 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 1:36:40) |
| 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:

Recommendations of the DUR Board	Commissioner's Final Determination
<p>Anticoagulants – oral 2:13:56</p> <p>Preferred Coumadin, Eliquis, Jantoven, Pradaxa, warfarin</p> <p>Non-preferred Xarelto</p>	
<p>Oral Agents for Pulmonary Arterial Hypertension (PAH) 2:15:29</p> <p>Preferred Letairis, Tracleer</p> <p>Non-preferred Adempas, Opsumit, Orenitram</p>	
<p>Agents for Opioid Dependence 2:16:41</p> <p>Preferred buprenorphine, Suboxone Film</p> <p>Non-preferred buprenorphine/naloxone tablet, Zubsolv</p> <p style="text-align: right;">Vote: 9 support, 1 oppose</p>	
<p>Opioid Antagonists 2:17:37</p> <p>Preferred naloxone syringe, naloxone vial, naltrexone, ReVia</p> <p>Non-preferred Evzio</p>	
<p>Sodium Glucose co-transporter 2 (SGLT2) Inhibitors 2:18:45</p> <p>Preferred Invokana</p> <p>Non-preferred Farxiga, Jardiance</p>	

Alpha-Glucosidase Inhibitors Preferred acarbose, Glyset Non-preferred Precose	2:19:20
Meglitinides Preferred nateglinide, repaglinide Non-preferred Starlix, Prandimet, Prandin	2:20:00

F. Drug Utilization Reviews

(Audio Cast Time 2:20:36 - 5:13:28)

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:

<p>Hepatitis C Virus – Clinical Criteria Review (vote 3:17:40–3:18:58) (pegylated interferon, ribavirin, boceprevir, simeprevir, sofosbuvir, telaprevir)</p> <p>Implement clinical criteria and/or point of service editing addressing:</p> <ul style="list-style-type: none"> ● FDA labeling and compendia supported use ● Prescriber experience and training ● Patient readiness and adherence ● Disease Prognosis and Severity <p style="text-align: right;">Passed Unanimously</p>
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2. Memantine ER (Namenda XR) - Clinical/Utilization Review (Audio Cast Time 3:20:18 - 3:56:36)

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	(vote 3:54:39–3:56:00)
Confirm diagnosis for the FDA-approved indication:	
<ul style="list-style-type: none"> • Dementia or Alzheimer’s Disease 	
Absence of covered diagnosis in patient’s claim history will require prescriber involvement.	
	Passed Unanimously
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Memantine ER (Namenda XR) – Clinical/Utilization Review	(vote 3:56:04–3:56:36)
Step Therapy: Trial with memantine immediate-release	
Override will require prescriber involvement.	
	Passed Unanimously

3. Tetrabenazine (Xenazine) - Clinical/Utilization Review (Audio Cast Time 4:10:22 - 4:30:10)

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	(vote 4:30:20 - 4:35:13)
Confirm diagnosis for the FDA and Compendia approved indications in patients ≥ 18 years:	
<ul style="list-style-type: none"> ▪ 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
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Tetrabenazine (Xenazine) – Clinical/Utilization Review	(vote 4:35:15 - 4:40:55)
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

(Audio Cast Time 4:41:22 - 5:13:28)

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:

Tasimelteon (Hetlioz) – Clinical/Utilization Review	(vote 4:51:50 - 5:12:28)
Confirm diagnosis for the FDA-approved indication:	
Non-24-hour sleep-wake disorder in totally blind patients only	
Absence of covered diagnosis in patient’s claim history will require prescriber involvement	
	Vote: 6 support, 3 oppose
Tasimelteon (Hetlioz) – Clinical/Utilization Review	(vote 5:12:32 - 5:13:28)
Quantity Limit:	
1 unit per day (30 units per 30 days)	
	Vote: 6 support, 1 oppose, 2 abstentions

G. Final Comments and Adjournment

Audio Cast Time (5:13:51 – 5:14:15)

Janet Zachary-Elkind

Meeting adjourned at 4:00 PM