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:

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 1:36:40)
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
Anticoagulants – oral 2:13:56 Preferred Coumadin, Eliquis, Jantoven, Pradaxa, warfarin Non-preferred Xarelto	Approved as Recommended
Oral Agents for Pulmonary Arterial Hypertension (PAH) 2:15:29 Preferred Letairis, Tracleer Non-preferred Adempas, Opsumit, Orenitram	Approved as Recommended
Agents for Opioid Dependence 2:16:41 Preferred buprenorphine, Suboxone Film Non-preferred buprenorphine/naloxone tablet, Zubsolv Vote: 9 support, 1 oppose	Approved as Recommended
Opioid Antagonists 2:17:37 Preferred naloxone syringe, naloxone vial, naltrexone, ReVia Non-preferred Evzio	Approved as Recommended
Sodium Glucose co-transporter 2 (SGLT2) Inhibitors 2:18:45 Preferred Invokana Non-preferred Farxiga, Jardiance	Approved as Recommended

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

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:

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

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: • 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 (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: ▪ 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 (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 patents 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

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:

- 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.