



New York State Medicaid Drug Utilization Review (DUR) Board Meeting Summary for November 19, 2015

The Medicaid DUR Board met on Thursday, November 19, 2015 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 00:24 - 03:11)

Department of Health

Janet Zachary-Elkind
Robert Correia, PharmD
Douglas Fish, MD
Anthony Merola, RPh, MBA
John Naioti, RPh

Alda Osinaga, MD
Robert Sheehan, RPh
Monica Toohey, RPh
Daniel O’Connell

DUR Board

Lisa Anzisi, PharmD
Nancy Balkon, PhD, NP
Donna Chiefari, PharmD
James Hopsicker, RPh, MBA
Renante Ignacio, MD

Jadwiga Najib, PharmD
Paula Panzer, MD
Michelle Rainka, PharmD
William Scheer, RPh
John Wikiera

SUNY – University at Buffalo

Holly Coe, PharmD
Michael P. Krajewski, PharmD, MLS
Diana Nagrecha, PharmD

Irene Reilly, PharmD
Barbara Rogler, PharmD, MS

B. Public Comment Period

(Audio Cast Time 03:11 - 00:30:07)

The following speakers provided public comment to the board:

- | | | |
|------------------------------|--|-------------------|
| 1. Catherine J Datto, MD, MS | AstraZeneca | Drugs for OIC |
| 2. Erin D. Gleason, Ph.D. | Vertex Pharmaceuticals | Kalydeco, Orkambi |
| 3. Robert Kaslovsky, MD | Albany Medical College | Kalydeco, Orkambi |
| 4. Reed Vreeland | Housing Works | Hepatitis-C |
| 5. Eric J Rude, MSW | NYC Dept. of Health and Mental Hygiene | Hepatitis-C |

C. Drug Utilization Review (DUR)

(Audio Cast Time 0:29:56)

1. Drugs for Opioid Induced Constipation (OIC)

(Audio Cast Time 0:30:08)

The board reviewed the treatment of opioid induced constipation and the place in therapy of the agents used in treating this condition. The review identified the FDA approved products used in the treatment of this condition along with additional compendia uses, dosage and administration, pharmacology, adverse reactions and interactions, their place in therapy, and respective cost. Comparative evidence between the newer agents and traditional laxatives was reviewed. Guidelines associated with opioids and pain as well as opioid prescribing were presented from the VA Administration/Department of Defense, the American Pain Society, the American Academy of Pain Medicine as well as the American Society of Interventional Pain Physicians. These guidelines stressed the need for increased fiber/fluid intake and the use of stool softeners and laxatives in the treatment of opioid related constipation. Utilization statistics were presented focusing on the use of these agents in both the Medicaid and Medicaid Managed Care programs. The report concluded by identifying that these agents are FDA approved for opioid induced constipation and that pretreatment guidelines for opioid induced constipation should include as first line treatment laxatives, stool softeners and non-pharmacologic measures.

The DUR Board recommended the following:

(Audio Cast Time 0:54:21)

Confirm diagnosis for the FDA-approved or compendia-supported indication(s).

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

Passed Unanimously

Step therapy-

Trial with an osmotic laxative, a stimulant laxative and a stool softener prior to use of lubiprostone (Amitiza®), methylnaltrexone (Relistor®), or naloxegol (Movantik™).

9 in-favor, 1 opposed, 1 abstention

Quantity limits based on FDA-approved labeling:

- Lubiprostone (Amitiza®): 2 capsules per day (60 capsules per 30 days)
- Methylnaltrexone (Relistor®):
 - Single-use vials and syringes (8 mg and 12 mg): 1 vial/syringe per day (30 vials/syringes per 30 days)
 - Kits (contains 7 pre-filled single-use syringes in 8 mg and 12 mg): 4 kits per 28 days
- Naloxegol (Movantik™): 1 tablet per day (30 tablets per 30 days)

Passed Unanimously

2. Kalydeco (ivacaftor), Orkambi (ivacaftor/lumacaftor) (Audio Cast Time 1:09:15)

The board reviewed the cystic fibrosis agents Kalydeco and Orkambi. The report focused on utilization across the Medicaid population. A background overview of cystic fibrosis and its causes was presented followed by a review of Kalydeco and Orkambi. For each agent their respective doses, pharmacology, safety and drug interactions, contraindications, precautions/warnings, drug cost, and place in therapy was presented. A comparative utilization review of Kalydeco and Orkambi utilization in the Medicaid and Medicaid Managed Care programs was presented for the period January 1, 2012 to June 30, 2015. The report highlighted the need for genetic mutation testing corresponding to the approved indication for each of the agents.

The DUR Board recommended the following: (Audio Cast Time 1:51:42)

Confirm diagnosis for the FDA-approved or compendia-supported indication(s).

Genetic testing required to verify appropriate mutation

- Absence of covered diagnosis in patient's claim history will require prescriber involvement

Passed Unanimously

Educational intervention to prescribers highlighting safety issues

Passed Unanimously

3. Erythropoietin-Stimulating Agents (ESAs)

(Audio Cast Time 1:53:47)

The board reviewed utilization of the erythropoiesis-stimulating agents within the Medicaid and Medicaid Managed Care prescription drug programs. Data was presented as a utilization review which identified the diagnoses associated with the use of these agents within both programs. The agents in this class were reviewed with respect to their market approval from the FDA, their dosage and administration, other compendia supported use, pharmacology, safety, risks identified in the labeled boxed warnings, contraindications, adverse reactions and identified drug interactions, and their place in therapy. Clinical guidelines from the National Comprehensive Cancer Network and the Kidney Disease Improving Global Outcomes respective to the use of these agents were also presented. A comparison of these two clinical guidelines was noted adding that neither of the guidelines make any specific recommendations regarding product selection.

The DUR Board recommended the following:

(Audio Cast Time 2:12:56)

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|---|
| Confirm diagnosis for the FDA-approved or compendia-supported indication(s). |
| <ul style="list-style-type: none">Absence of covered diagnosis in patient's claim history will require prescriber involvement |
| Passed Unanimously |
| Educational intervention to prescribers highlighting safety issues. |
| Passed Unanimously |

4. Daraprim (pyrimethamine)

(Audio Cast Time 2:14:40)

The board reviewed utilization of pyrimethamine across the NYS Medicaid population - fee for service and Medicaid managed care programs. Specific attributes of the drug such as FDA labeled and compendia-supported indications for use, dose and administration, pharmacology, place in therapy (toxoplasmosis, malaria, and PCP treatment), and safety were outlined in the presentation. The utilization analysis reviewed age/gender distribution, diagnosis, and dosing frequency of the drug's use within fee-for-service and managed care programs. As the drug is known to deplete patient folate levels the concurrent use of leucovorin or folic acid with pyrimethamine was also discussed.

The DUR Board recommended the following:

(Audio Cast Time 2:44:22)

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|---|--------------------|
| Diagnosis requirement: Confirm diagnosis for the FDA-approved or compendia-supported indications | |
| <ul style="list-style-type: none">Absence of covered diagnosis in patient's claim history will require prescriber involvement | |
| | Passed Unanimously |
| Require concurrent utilization of leucovorin | |
| | Passed Unanimously |

D. DUR Program Updates

1. Ending the AIDS Epidemic in New York State

(Audio Cast Time 2:46:53)

Daniel O'Connell of the AIDS Institute presented an overview of the Ending the AIDS Epidemic in New York State initiative. The major goal of the program is to reduce the occurrence of new HIV infections. He described for the board a three point plan to achieve this goal:

1. Identify persons with HIV who remain undiagnosed and link them to health care.
2. Link and retain those with HIV in health care to maximize virus suppression and prevent transmission.
3. Support Pre-Exposure Prophylaxis (PrEP) for persons who engage in high risk behaviors.

New and expanded programs were described in concert with a budgetary allotment which emphasized New York's commitment to ending this epidemic. The process of taking key metrics and systematically tracking this data at state and local levels with publically available results was also presented.

2. Hepatitis-C Drug Utilization

(Audio Cast Time 3:28:45)

The board was presented an Update on the Management of Chronic Hepatitis-C Infection which evaluated the utilization of the direct acting antiviral agents. The

presentation included a current listing of the available direct acting antiviral agents which identified in addition to the drug name the FDA approval date, the pharmacologic class, the FDA indications, the dosage forms and the adult dose. Included was a detailed review of the changes in newly marketed agents, product labeling updates, new postmarketing clinical information reported, agents removed or scheduled to be removed from the marketplace as well as changes in the AASLD/IDSA guidelines. Utilization review data focused on diagnosis, medical testing inclusive of liver biopsy, imaging (ultrasound, CT, fibroscans, etc.) genotyping, liver function panels performed, as well as the existence of concomitant conditions and comorbidities, duration of therapy and recipient adherence.

3. Opioid Utilization and Clinical Editing – buprenorphine, methadone

(Audio Cast Time 4:22:20)

The board reviewed a cumulative update on the edits initiated from past actions taken by the board with focus on the utilization of oral buprenorphine products and methadone. Edits evaluated included quantity limits placed on oral buprenorphine monotherapy, quantity limits placed on dispensed amounts of buprenorphine/naloxone, concomitant usage of buprenorphine with opioids or benzodiazepines, quantity edits and their effect on the use of methadone, the effect of edits on beneficiaries receiving methadone currently taking four or more opioid prescriptions within a 30-day period, and edits on the concomitant use of methadone with long and short acting opioids. Overall, opioid clinical edits have resulted in increased compliance with duration and quantity limits, and decreased utilization of opioids concomitantly used with benzodiazepines. The point-of-sale (POS) clinical edits have had a positive impact on the safe and effective management of opioids

4. Influenza Vaccination among Asthmatics in the Fee-for-Service Program

(Audio Cast Time 4:44:02)

The board reviewed a report of the Effectiveness of a Mailed Letter Intervention to Improve Influenza Vaccination Rates Amongst Fee-For-Service Asthmatics conducted by the State University of New York at Buffalo (UB) as part of the New York Medicaid retrospective drug utilization review (RetroDUR) program. The report included an overview of the RetroDUR program operation, overall goals of the program which include optimizing drug utilization and identifying abuse, and the specifics of a case study performed by UB. The case study involved a mailed letter intervention to physicians and pharmacies in order to improve influenza vaccination rates among Medicaid fee-for-service asthmatics. A summary of the report reported an approximate twenty percent increase in the influenza vaccination rate in intervention groups and a

greater increase in the vaccination rate in the intervention group compared to the control group.

5. Prescriber Education Program (PEP)

(Audio Cast Time 5:16:32)

The board reviewed an update of the PEP program highlighting the recently developed hyperlipidemia module consisting of 4 key messages. The update noted that academic educators are available to visit interested prescribers when further information is needed. Handouts are made available where the key messages are further detailed and provide the prescriber with a specific clinical and educational application. Educational modules for chronic non-cancer pain, diabetes, hypertension and hyperlipidemia are currently available through the PEP. A Synagis module is also available through the program web-site. Visits by the program's academic educators are in the form of a 1:1 (practitioner/ educator), small group (i.e. office practices), or in the form of a grand rounds presentation.

E. Final Comments and Adjournment

(Audio Cast Time 5:20:30)

Janet Zachary-Elkind

Meeting adjourned at 3:30 PM