New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for September 19, 2019

The Medicaid DUR Board met on Thursday, September 19, 2019 from 9:00am to 4:00pm. 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

Department of Health (DOH)
Elena Andi
Douglas Fish, MD - Chairperson
Robert Correia, PharmD
Anthony Merola, RPh, MBA

Robert Sheehan, RPh
Mark Shutts
Monica Toohey, RPh
Janet Zachary-Elkind

DUR Board Members
Donna Chieffari, PharmD
Lisa Anzisi, PharmD
Peter Deane, MD
Jacqueline Jacobi, RPh
Jill Lavigne, PhD
Peter Lopatka, FSA

Jadwiga Najib, PharmD
John Powell, FSA
Casey Quinn, PhD
Tara Thomas, RPh, MBA, MPA
Jamie Wooldridge, MD

State University of Buffalo (SUNY)
Linda Cantanzaro, PharmD
Holly Coe, PharmD

Terry Dunn, PharmD
Barbara Rogler, PharmD

B. Pharmacy Program Updates

1. Drug Cap Update
   The update was presented by Janet Zachary-Elkind and Mark Shutts. The presentation provided background information, status updates, State Fiscal Year (SFY) pharmacy expenditures to date for 2019 and the SFY 2020 projection. A recap of the statutory provisions under § 280 of the Public Health Law was reviewed. New statutory provisions for SFY 2019-2020 included changes in rebate negotiation process, administrative efficiencies and transparency provisions. For SFY 2019, pharmacy expenditures along with drug cap savings
was presented in graphic and tabular format. Based on SFY 2020 projections, pharmacy expenditures are expected to exceed the Medicaid Drug Cap.

2. The SUPPORT for Patients and Communities SUPPORT Act

Background information associated with the SUPPORT Act was presented by Elena Andi. The report focused on section 1004 of the Act - Medicaid drug review and utilization. The Act includes provisions for all Medicaid Programs as well as parameters for drug utilization review practices. The provisions are required for both Medicaid Fee-for-Service (FFS) and Managed Care Plans (MCPs). An overview of select Medicaid provisions was presented. The overview identified the following:

- Allowance for states to expand substance use disorder (SUD) programs and receive enhanced federal matching.
- Requires Health and Human Services Secretary to issue guidance for improving care for infants with neonatal abstinence syndrome and their families in addition to State options for SUD telehealth services and Medicaid services for non-opioid pain management.
- Extend federal matching rate for innovative Medicaid health home activities designed specifically for beneficiaries with SUD.
- Requires Medicaid programs to cover all medication-assisted treatment (MAT) services beginning October 1, 2020 through September 2025. This includes all FDA – approved MAT drugs, and related counseling and behavioral health services.

As presented, specific DUR provisions become effective October 1, 2019. Those provisions were identified as follows:

- Safety edits for subsequent fills for opioids and a review process which indicates subsequent fills in excess of any state limitation.
- Safety edits on the maximum daily morphine equivalent (MME) and an automated claims review process that indicates when that limitation is exceeded.
- An automated claims review process that identifies when prescribed opioids and benzodiazepines or antipsychotics are used concurrently.
- A program to monitor utilization of antipsychotic medications for Medicaid children 18 and under, inclusive of foster care children, and report to HHS annually on those activities.
- A program to monitor fraud or abuse of controlled substances by enrollees, prescribers and pharmacists.

It was reported that the above provisions are in place for FFS and that the 2019 CMS Annual DUR Survey of MCPs is being reviewed for compliance. Early indications suggest the provisions are in place for MCPs.
C. Drug Utilization Reviews (DUR)

1. Opioid Utilization as related to the SUPPORT Act

This review was presented to the DUR Board by Dr. Rogler. The objectives of the SUPPORT Act (section 1004) as they apply to the New York Medicaid Program were reiterated. The tools used by the Medicaid FFS program to comply with those requirements were illustrated and focused on the Prospective and Retrospective DUR (ProDUR/RetroDUR) initiatives.

The ProDUR program uses automated edits at the point of service designed to address utilization within the Medicaid program. Dr. Rogler proceeded to describe how this program and the edits impacted opioid utilization; decreasing opioid use from SFY 2014 to the present.

The RetroDUR program retrospectively evaluates drug utilization using criteria including those developed by the DUR Board. The program is managed by a team of pharmacists from SUNY at Buffalo. Drug therapy concerns involving opioids are identified, and targeted letters are sent to providers as well as pharmacists. Trends involving suspected fraud are extracted and sent to the Office of Medicaid Inspector General.

The report summarized the intent of the SUPPORT Act (section 1004) on the Medicaid Program - reduce opioid related fraud, misuse and abuse. Dr. Rogler also noted that the DUR Board has been actively involved in recommending ProDUR activity regarding opioid use and misuse prior to the requirements of section 1004. This activity has also included the use of RetroDUR activity to address and reduce opioid use, abuse and fraud.

<table>
<thead>
<tr>
<th>DOH Recommendation to the DUR Board</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Utilization Review: Opioid Utilization as related to the SUPPORT Act</strong></td>
</tr>
<tr>
<td><strong>DOH Recommendation #1:</strong></td>
</tr>
<tr>
<td>Prior authorization is required for opioid-naïve patients exceeding a morphine milligram equivalent (MME) of 90mg per day.</td>
</tr>
<tr>
<td>Passed Unanimously</td>
</tr>
</tbody>
</table>
2. Antipsychotic Utilization in Children as related to the SUPPORT Act

Audio Cast Time 1:13:39 to 2:01:25

Dr. Rogler presented on the use of antipsychotics in children as it relates to the requirements found in the SUPPORT Act. Current clinical advisories on the use of these agents from the State's Office of Mental Health, Division of Children and Family Services were identified. DUR Board agenda topics relating to antipsychotic use in children discussed in 2013 and 2014 were summarized as were the resulting ProDUR clinical edits.

A utilization review of antipsychotic use in children was presented for SFYs 2018 and 2019. Data was provided from both the FFS program and MCP members, inclusive of foster children. Utilization information was presented, inclusive of age, metabolic monitoring and polypharmacy.

The report provided the following recommendations:

- Continue to monitor the use of antipsychotics in children providing annual reports to the DUR Board.
- Develop an educational letter to encourage metabolic monitoring for members receiving antipsychotic therapy.
- For members < 21 years of age receiving antipsychotic polypharmacy, consider reducing the current edit for oral second-generation medications in members from greater than or equal to three antipsychotic agents for > 180 days to greater than or equal to two antipsychotics medications for > 90 days.

<table>
<thead>
<tr>
<th>DOH Recommendations to the DUR Board</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Audio Cast Time</strong> 1:48:57</td>
</tr>
<tr>
<td><strong>Drug Utilization Review:</strong> Antipsychotic Utilization in Children as related to the SUPPORT Act</td>
</tr>
<tr>
<td><strong>DOH Recommendation #1:</strong></td>
</tr>
<tr>
<td>Send a targeted prescriber educational letter regarding antipsychotic therapy and metabolic monitoring for patients less than 21 years of age.</td>
</tr>
<tr>
<td>Passed unanimously</td>
</tr>
</tbody>
</table>
DOH Recommendations to the DUR Board

DOH Recommendation #2

Prior authorization is required for patients less than 21 years of age when there is concurrent use of two or more different oral antipsychotics for greater than 90 days.

DOH to send a notification letter to prescribers who could be impacted by this prior authorization requirement.

Passed unanimously

3. Opioid and Antipsychotic Concurrent Utilization as related to the SUPPORT Act

This utilization review was presented by Dr. Rogler and Dr. Holly Coe. Dr. Coe introduced the topic by explaining the purpose of the report - to evaluate the concurrent use of antipsychotics and opioid medications in both the Medicaid FFS and MCP programs.

Background information was provided including FDA black box warnings, the position of CMS in reducing the concurrent use of opioids and antipsychotics, and an increase focus/awareness on coordination of care. Current clinical criteria practices and programs (ProDUR and RetroDUR) utilized by the FFS program was described as already consistent with the positions of FDA and CMS as they pertained to opioids and antipsychotics.

A utilization analysis of the concurrent use of these agents was presented, including the number of members receiving an opioid and an antipsychotic concurrently during a consecutive 90-day period. Dr. Coe summarized the presentation and recommended that the DOH continue to monitor concurrent use of these agents, develop an educational letter to prescribers highlighting the SUPPORT Act requirements and update the educational modules used in prescriber detailing promoted by the Medicaid Prescriber Education Program.

Dr. Rogler then presented a DUR focusing on the use of the RetroDUR aspect of the Medicaid Program with its applications in reviewing the concurrent use of opioids and antipsychotics or benzodiazepines. Dr. Rogler discussed the role RetroDUR criterion associated with the concurrent prescribing of opioids and antipsychotics and the concurrent prescribing of opioids and benzodiazepines. As a result, educational letters were sent to both pharmacists and physicians (380 letters were sent focusing on the concurrent use of opioids and antipsychotics; 448 letters were sent to pharmacies and physicians focusing on
the concurrent use of opioids and benzodiazepines). It was recommended that the RetroDUR process continue to be utilized in reviewing concurrent use as noted above.

<table>
<thead>
<tr>
<th>DOH Recommendations to the DUR Board</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Utilization Review: Opioid and Antipsychotic Concurrent Utilization as related to the SUPPORT Act</strong></td>
</tr>
</tbody>
</table>

**DOH Recommendation # 1:**

Send a targeted prescriber educational letter highlighting the Support Act requirements addressing the concurrent use of antipsychotic and opioid medications, and the importance of mental health treatment and coordination of care.

Passed unanimously

---

The DUR Board recessed for lunch at 11:55 am

The DUR Board returned from lunch at 1:15 pm

4. Leukotriene Modifier (LM) utilization in the treatment of asthma

This utilization review was presented by Dr. Terry Dunn. The purpose was to evaluate the utilization of leukotriene modifiers in the treatment of asthma. A brief description of asthma and the role of cysteinyi leukotrienes, the mechanism of action, drug interactions, warnings and adverse reactions, along with their place in therapy was addressed. A comparison of the 2018 and 2019 Global Initiative of Asthma along with guidelines from the National Heart, Lung and Blood Institute was reviewed.

Utilization data reflected the general utilization of LMs with and without a diagnosis of asthma, as well as their combined therapy with and without short acting beta agonists, inhaled corticosteroids as well as inhaled corticosteroids and long acting beta agonists. As presented by Dr. Dunn, 2.4% of Medicaid members with asthma using LM did not have a claim for another agent used to treat asthma.
It was recommended that the DUR Board consider evaluating the use of medications used to treat asthma at a future Board meeting in view of the newer asthma treatment guidelines published in 2019.

<table>
<thead>
<tr>
<th>DOH Recommendations to the DUR Board</th>
<th>Audio Cast Time 3:18:21</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Utilization Review: Leukotriene Modifiers used in the Treatment of Asthma</strong></td>
<td></td>
</tr>
<tr>
<td><strong>DOH Recommendation #1</strong></td>
<td></td>
</tr>
<tr>
<td>Send a targeted prescriber educational letter regarding Leukotriene Modifier use relative to asthma treatment guidelines.</td>
<td></td>
</tr>
<tr>
<td><strong>DUR Board vote:</strong> Yes 11 No 0 Abstentions 1</td>
<td></td>
</tr>
</tbody>
</table>

**D. Clinical Editing Updates**

1. Utilization of antiretroviral combinations (for the treatment of HIV/AIDS) and associated drug interactions

   - Dr. Cantanzaro presented a review of anti-retroviral (ARV) agents (used in the treatment of patients with HIV/AIDS) and associated drug interactions. A brief background was provided stating that current available ARVs can interact with co-administered drugs via pharmacokinetic or pharmacodynamic mechanisms. The information presented focused on ARV combinations that should not be co-administered per FDA labeling. The Medicaid Data Warehouse (MDW) used a coding system, similar to FDB/NCPDP (First Data Bank/National Council for Prescription Drug Programs), to categorize DDI based on severity of clinical significance but it was noted that severity level descriptions have changed. Recently, DUR point-of-service edits have been implemented to identify ARV-ARV drug to drug interactions as level 1 interactions that should be avoided but are not necessarily captured as level 1 drug to drug interactions by FDB programming. As presented, current POS (point of service) system editing has reduced the number of claims with ARV combinations with a level 1 severity designation in the Medicaid Data Warehouse.

A series of slides were presented which outlined the various ARV product classes used to treat HIV/AIDS. This was followed by utilization statistics from the FFS and MCP programs which showed a general increase in the utilization of ARVs from SFY 2014 through SFY 2019.
Dr. Cantanzaro summarized her findings over the period from 2014 to 2019. Most of the claims for ARV-ARV interactions identified during SFY 2014 - 2019 involved concomitant, single tablet regimens which the FDA labeling for these agents does not support. The overall rate of ARV-ARV drug to drug interactions was low and occurred mainly in the MCP population. The majority of ARV-ARV drug to drug interactions were identified by drug utilization review point-of-service edits, and not as severity levels provided by FDB.

It was recommended that the current process of updating the ARV-ARV drug interactions DUR point of service editing should continue as new ARVs or new post marketing drug interaction data become available.

E. Final Comments and Adjournment

Janet Zachary-Elkind, Deputy Director
Douglas Fish, MD - Chairperson
Anthony Merola, RPh, MBA

Contact for post meeting questions: DUR@health.ny.gov or 518-486-3209

Meeting adjourned at 2:30pm