

**New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for November 18, 2021**

The Medicaid DUR Board met on Thursday, November 18th, 2021 from 9:00am to 1:00pm.

The meeting was available for public viewing by way of live audio-video webcast and Meeting Room 2, Empire State Plaza, Concourse Level, Albany, New York

An archived webcast of the meeting proceedings is available on the Department of Health website: <http://www.health.ny.gov/events/webcasts/>

A. Welcome and Introductions

Approximate Webcast Time 00:00:40

Department of Health

Douglas Fish, MD - DUR Board Chairperson
Tracy Berger, RPh
Robert Correia, PharmD
Kimberly Leonard, RPh
Kimberly Laurenzo, PharmD

Anthony Merola, RPh, MBA
Jacqueline Nahlik
Robert Sheehan, RPh
Monica Toohey, RPh

DUR Board Members

Lisa Anzisi, PharmD
Donna Chiefari, PharmD
Joseph Chiarella, MD
Marla Eglowstein, MD
James Hopsicker, RPh, MBA
Renante Ignacio, MD
Brock Lape
Jill Lavigne, PhD, MS, MPH
Peter Lopatka, FSA

Jadwiga Najib, PharmD
Michael Pasquarella, PharmD
Casey Quinn, PhD
Asa Radix, MD
Gloria Rodriguez, MD
Tara Thomas, RPh, MBA, MPA
Deborah Wittman, PharmD

SUNY – University at Buffalo

Holly Coe, PharmD
Irene Reilly, PharmD
Barbara Rogler, PharmD

B. Public Comment Period

There were no speaker requests therefore no public comment period.

C. Pharmacy Program Updates

Approximate Webcast Time 00:08:30

1. Statewide Formulary for Opioid Dependence Agents and Opioid Antagonists
- Tracy Berger, RPh

The purpose of the presentation was to provide an overview of the initiative including the implementation timeline, formulary structure, clinical criteria, program impact, and pre- and post-implementation actions. The following information was included in the update:

Beginning October 1, 2021, the Department of Health implemented a single, statewide formulary for the Opioid Antagonists and Opioid Dependence Agents therapeutic classes which applies to both Medicaid Managed Care (MC) and Medicaid Fee-for-Service (FFS) programs.

Coverage parameters of both classes are now consistent across the Medicaid Program (MC and FFS). Preferred products (within the two classes) do not require prior authorization (PA) unless coverage parameters are exceeded. Non-preferred products require a PA. Standard criteria are being used for approval of non-preferred agents on the statewide formulary.

Patient access to medications used to treat substance use disorder did not change and this initiative should provide better access due to the formulary alignment across the FFS and MC. Decreases in administrative burdens for pharmacies and providers should be realized as the initiative progresses.

Pre-implementation actions included internal and external stakeholder outreach and communications. Post-implementation actions addressed specific concerns and attempted to mitigate and resolve unforeseen issues that occur with any major procedural change.

A period for questions followed the presentation.

2. Respiratory Syncytial Virus (RSV) Season and palivizumab - Irene Reilly, PharmD

The purpose of the presentation was to review the incidence of the respiratory syncytial virus (RSV) in New York State (NYS) and the use of palivizumab for RSV prevention. The following information was included in the update:

Background including virus characteristics, the type of infection the virus causes, the hospitalization sequelae, as well as palivizumab being the only FDA approved drug utilized to prevent RSV.

RSV season in NYS, historically, begins in October and ends March 31. The 2020-2021 season was extended due to the high prevalence of RSV.

The American Academy of Pediatrics RSV treatment guidelines was described as being consistent with current criteria established in Medicaid program.

A retrospective utilization review of palivizumab covered a period from October 1, 2015, to July 31, 2021 and included data from both the FFS and MC programs.

Utilization of palivizumab was consistent over the FFS and MC populations with the majority of members being 0 to 12 months of age at the start of the RSV season.

Greater than 90% of members had five or fewer palivizumab claims within each season analyzed with the exception of 2020-2021 (10 months / through July), where greater than 90% of members had six or fewer claims.

It was recommended to maintain the current clinical criteria for use of palivizumab and to monitor RSV activity and guidance from the Center for Disease Control (CDC) and the American Academy of Pediatrics as related to the 2021-2022 RSV season.

A period for questions followed the presentation.

3. Direct Acting Antivirals (DAA) for Hepatitis C Virus (HCV) – Barbara Rogler, PharmD

The purpose of the presentation was to review data presented in the NYS Department of Health Hepatitis B and C Annual Reports and evaluate the utilization of the Hepatitis C DAA agents in the Medicaid program. The following information was included in the update:

Background information on the pathogenesis of the disease, methods of exposure, and the development of chronic disease.

A historical disease treatment guideline from 1989 to 2021, emphasizing treatment progress.

A chronology of the HCV DAA agent class review by the DUR Board.

The initial workgroup included the Department of Health Office of Health Insurance Programs, the AIDS Institute, the Medicaid MC Organizations and individual practitioners involved in the treatment of chronic HCV.

A historical timeline of clinical criteria and preferred drug status.

A retrospective utilization review of the HCV DAA agents included data from 2011 through 2021. The data provided information including the number of Medicaid members using HCV DAA agents along with member gender, age, and comorbidities.

A period for questions followed the presentation.

4. Supplemental Rebate Initiatives – Amir Bassiri

The purpose of the presentation was to provide an overview of the supplemental rebate authorities with focus on three areas: Drug Cap, High-Cost Drugs, and the Fee for Service Preferred Drug Program (FFS PDP). The following information was included in the update:

Differences between the Drug Cap and High-Cost Drugs, the authorizing statute, criteria for drug identification, and a comparison of the operational processes for the two programs.

Accomplishments to date noting that new contracts are yielding additional supplemental rebates.

The Drug Cap process includes a value assessment of drug costs which has enhanced the rebate negotiation process.

Early indications suggest the Drug Cap initiative is providing additional rebates and reducing spending without limiting access to high-cost drugs.

Anticipated review periods for the supplemental rebate programs (FFS PDP, Drug Cap and High-Cost Drug) moving forward.

A period for questions followed the presentation.

D. Drug Utilization Review

Approximate Webcast Time 01:35:45

1. Central Nervous System (CNS) Stimulants – Holly Coe, PharmD

The purpose of the review was to assess the utilization of Central Nervous System (CNS) stimulants used concurrently with other controlled substances, specifically, benzodiazepines and opioids. The following information was included in the drug utilization review:

Background information referencing the Substance Abuse and Mental Health Services Administration (SAMHSA), the National Surveys on Drug Use and Health (NSDUH), and published data from the National Vital Statistics System (2020) by the Center for Disease Control (CDC) National Center for Health Statistics.

Treatment guidelines for ADHD, insomnia, and chronic pain which do not address the concurrent use of these agents.

A utilization analysis for the period April 2010 through March 2021 which showed that utilization of CNS stimulants and drugs for the treatment of Opioid use Disorder (OUD) increased, whereas the utilization of benzodiazepines and opioids decreased (over the analysis period).

Data focused on concurrent use of greater than or equal to 30 days (during State Fiscal Year 2020 -2021). The data showed that the highest incidence of concurrent use (for greater than or equal to 30 days) was with a CNS stimulant and a benzodiazepine.

Concurrent use of CNS stimulants with other controlled substances (such as benzodiazepines and opioids) has been increasing in recent years.

The drug utilization review recommendations were as follows:

1. Consider requiring a prior authorization (PA) when a CNS stimulant is prescribed for a member currently utilizing a benzodiazepine (excluding injectable or rectal formulations) for ≥ 30 days or an opioid (full agonist) for ≥ 30 days.

2. Consider requiring a PA when a benzodiazepine (excluding injectable or rectal formulations) is prescribed for a member currently utilizing a CNS stimulant.
3. Consider requiring a PA when an opioid (full agonist) is prescribed for ≥ 7 days for a member currently utilizing a CNS stimulant.*
4. Consider requiring a PA when a CNS stimulant is prescribed for a member currently utilizing buprenorphine for opioid use disorder (OUD).**

*PA would not be required when an opioid is prescribed for acute pain (e.g., 7-day supply) for a member currently utilizing a CNS stimulant

**PA would not be required when buprenorphine is prescribed for OUD for a member currently utilizing a CNS stimulant

A period for questions followed the presentation.

The DOH recommendations to the DUR Board were presented as follows:

DOH Recommendations to the DUR Board
<p>Central Nervous System Stimulants – Concurrent use with other Controlled Substances:</p> <p>DOH Recommendation #1: Prior authorization will be required when a CNS stimulant is prescribed for a member currently utilizing a benzodiazepine or an opioid for greater than or equal to 30 days.</p> <p>Vote: In favor 17 No 0 Abstaining 0</p> <p>-----</p> <p>DOH Recommendation #2: Prior authorization will be required when a benzodiazepine is prescribed (for greater than a 7-day supply) for a member currently using a CNS stimulant.</p> <p>The DOH recommendation was modified by DUR Board:</p> <p>DUR Board Recommendation #2: Prior authorization will be required when an initial benzodiazepine is prescribed (for greater than a 14-day supply) for a member currently utilizing a CNS stimulant.</p> <p>Vote: In favor 16 No 0 Abstaining 0</p> <p>-----</p> <p>DOH Recommendation #3: Prior authorization will be required when an opioid is prescribed (for greater than a 7-day supply) for a member currently using a CNS stimulant.</p> <ul style="list-style-type: none"> • PA will not be required when an opioid is prescribed for acute pain (less than or equal to a 7-day supply) for a member currently using a CNS Stimulant.

- PA will not be required when Medication Assisted Therapy is prescribed for opioid use disorder for a member currently using a CNS stimulant.

The DOH recommendation was modified by DUR Board

DUR Board Recommendation #3:

Prior authorization will be required when an initial opioid is prescribed for a member currently utilizing a CNS stimulant.

- PA will not be required when an opioid is prescribed for acute pain (less than or equal to a 7-day supply) for a member currently utilizing a CNS stimulant.
- PA will not be required when Medication Assisted Therapy is prescribed for Opioid Use Disorder for a member currently utilizing a CNS stimulant

Vote: In favor 16 No 0 Abstaining 0

E. Final Comments and Adjournment

Approximate Webcast Time 02:54:10

Douglas Fish, MD
Kimberly Leonard, RPh
Anthony Merola, RPh, MBA

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

Meeting adjourned at 12:15pm