The New York State Medicaid Drug Utilization Review Program Annual Report to the Governor and Legislature

Reporting Period: October 2021 through September 2022

I. Introduction

The New York State Medicaid Drug Utilization Review (DUR) Program submits an annual report to the Governor and Legislature pursuant to the requirements in the State's Social Services Law, Article 5, Title 11-C and Section 1927(g)(3)(D) of the Social Security Act. While most Medicaid Program pharmacy services are provided to members through their managed care plans, this report pertains solely to the Fee-For-Service (FFS) component of the Medicaid pharmacy program. Managed care plans are responsible for managing their individual DUR Programs.

The DUR Program is composed of two separate but complementary components:

- Prospective Drug Utilization Review (ProDUR) Program, and
- Retrospective Drug Utilization Review (RetroDUR) Program

The ProDUR Program is a point-of-service monitoring system that analyzes pharmacy claims during the claims adjudication process. The system can identify drug related problems such as therapeutic duplication, drug-disease contraindications, drug interactions, incorrect dosage or duration of treatment, drug allergy, overutilization, and underutilization. In addition, the system can identify drug therapy related to member demographics including pregnancy, age, and gender. If the system identifies a potential drug related problem, the pharmacy receives an on-line warning message. The pharmacist can then determine the appropriate action prior to dispensing.

The RetroDUR Program is designed to improve prescribing trends by alerting providers through provider education. The Program uses predetermined clinical criteria to generate case reviews of select members using claims data. Medical and pharmacy claims information is evaluated for safety and clinical appropriateness. If inappropriate drug therapy is identified, an intervention letter is sent to prescribers and/or pharmacists detailing the potential drug therapy problem. The drug related problem may include therapeutic duplication, drug-to-disease contraindications, drug-to-drug interactions, incorrect drug dosage or duration of drug treatment, and/or clinical concerns.

Federal legislation that requires a state to implement a DUR Program also requires states to establish DUR Boards. The NYS Medicaid DUR Board establishes medical standards and clinical criteria for the Medicaid Pharmacy Program. The DUR Board is comprised of health care professionals appointed by the Commissioner and includes physicians and pharmacists that actively practice in New York.

Responsibilities of the DUR Board include:

- The establishment and implementation of medical standards and criteria for the retrospective and prospective DUR Program.

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- The development, selection, application, and assessment of educational interventions for prescribers and pharmacists to improve care.
- The collaboration with managed care organizations to address drug utilization concerns and to implement consistent management strategies across the fee-for-service and managed care pharmacy benefits.
- The review of therapeutic classes subject to the Preferred Drug Program.

The legislative authorities of the DUR Board are provided within the following State statues:

- Medicaid Drug Utilization Review – Social Service Law, Article 5, Title 11-C https://www.nysenate.gov/legislation/laws/SOS/A5T11-C
- Preferred Drug Program - Public Health Law, Article 2A, Title I, Section 272 https://www.nysenate.gov/legislation/laws/PBH/272
- Clinical Drug Review Program – Public Health Law, Article 2A, Title I, Section 274 https://www.nysenate.gov/legislation/laws/PBH/274
- Medicaid Drug Cap – Public Health Law, Article-2A, Title II, Section 280 https://www.nysenate.gov/legislation/laws/PBH/A2-AT2
- Medicaid High-Cost Drug – Social Services Law, Article 5 Title 11, Section 367-A https://www.nysenate.gov/legislation/laws/SOS/367-A

II. DUR Educational Programs

In addition to the RetroDUR program, the Drug Information Response Center (DIRC) provides evidence-based information on pharmacotherapy to prescribers. Pharmacotherapy related questions can be submitted by prescribers and evidence-based responses are prepared by DIRC pharmacists. Below is a summary of topics addressed by the DIRC:

- Can oral investigational antiviral therapy be used concurrently with monoclonal antibodies or Veklury (remdesivir) for treatment of COVID-19?
- Information on repeat doses of oral therapy/monoclonal antibodies for COVID-19.
- What is the duration of therapy for any of the long COVID treatments?
- Fidelis' policy on dose optimization of chemotherapy.
- American Society of Pain and Neuroscience (ASPN) guidelines on management of cancer-associated pain.
- American Gastroenterological Association (AGA) guidelines on management of ulcerative colitis.
- Clinical trials and/or outcomes for patient on a stable dose of corticosteroids before treatment with the "exon-skipping" therapies for Duchenne muscular dystrophy (DMD).
- American Academy of Neurology (AAN) guideline on dopaminergic therapy for motor symptoms in early Parkinson Disease.
- Global Initiative for Chronic Obstructive Lung Disease (GOLD) guideline on management of COPD.
- Center for Disease Control (CDC) guideline on pre-exposure prophylaxis for HIV.
- An analysis of the financial impact of obesity and weight-loss medications.
- What are the pros and cons of weight-loss medication, including effectiveness, safety, and outcomes in comorbid conditions.
- An overview of Imcivree (setmelanotide).
- American Health Association (AHA)/ American College of Cardiology (ACC) / Heart Failure Society of America (HFSA) guideline for management of heart failure.

III. DUR Interventions

During the reporting period, there were 18.7 million on-line/point of service pharmacy claims processed. Approximately 1.9 million ProDUR warnings were issued, in which the pharmacy was alerted to potential drug related problems during the claims adjudication process.[1] The most common ProDUR warnings were associated with therapeutic duplication of therapy, drug pregnancy alert, early refill requests, and drug interactions. Below is a summary of ProDUR interventions:

ProDUR Warning Description	Number of Warnings Issued to Pharmacies	Number of Warnings Overridden at the Pharmacy#	Estimated Number of Alternations in Pharmacy Therapy^
Therapeutic Duplication	2,046,242	1,313,125	733,117
Drug Pregnancy Alert	1,728,442	0	1,728,442
Drug Age Precaution	48,308	0	48,308
Low Dose Alert	125,569	0	125,569
High Dose Alert	276,517	0	276,517
Early Refill	1,667,691	78,819	1,588,872
Drug to Drug Interaction	1,921,186	151,384	1,769,802
Inferred Drug Disease Precaution	1,013,254	0	1,013,254

Only severity level one warnings (i.e., therapeutic duplication, early refill and drug to drug interaction) require pharmacy override responses.

^ The number of warnings may include more than one alert per claim or multiple pharmacy overrides within the same claim transmission.

The RetroDUR process identified approximately 7,700 members who met criteria for a drug related problem and generated an intervention/educational letter. Over 12,000 intervention/educational letters were sent to providers (i.e., prescribers and pharmacies).[4] Below is a summary of RetroDUR interventions:

RetroDUR Clinical Criteria Description	Number of members selected for intervention	Number of intervention letters sent to providers*
Concurrent gabapentinoids & CNS depressants	608	1,540
Antipsychotic use in convulsive disorders	193	405
Chronic use of proton pump inhibitors	250	279
Concurrent opioids & benzodiazepines – SUPPORT Act**	126	262
Duplicate therapy of atypical antipsychotics	166	247
Asthma & lack of controller medication	131	240

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Concurrent opioids & antipsychotics - SUPPORT Act**	105	234
Concurrent duloxetine & other serotonergic drugs	128	225
Cholesterol guidelines in diabetic patients age 40-75	146	207
Concurrent opioids & gabapentin (>900mg/day)	91	181
Total all letters	7,683	12,163

*A single drug related problem may result in educational letters being sent to more than one provider.

**Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act [5]

IV. DUR Board

DUR Board members are appointed by the Commissioner of Heath and consists of nineteen (19) members as follows:

- One (1) chairperson representing the Department of Health.
- Five (5) licensed and actively practicing physicians.
- Five (5) licensed and actively practicing pharmacists.
- Two (2) drug utilization review experts, at least one of whom is a pharmacologist.
- Two (2) consumers or consumer representatives of organizations with a regional or statewide constituency and who have been involved in activities related to health care consumer advocacy.
- Two (2) health care economists.
- One (1) actuary.
- One (1) member from the New York State Department of Financial Service.

Drug Utilization Review (DUR) Board Membership (2021)

- Lisa Anzisi, PharmD, MS, Pharmacist
- Joseph Chiarella, MD, Physician
- Donna Chiefari, PharmD, Drug Utilization Review Expert
- Marla Eglowstein, MD, Consumer Representative
- Douglas Fish, MD, Chairperson
- James R. Hopsicker, RPh, MBA, Pharmacist
- Renante Ignacio, MD Physician
- Brock Lape, Consumer Representative
- Jill Lavigne, PhD, MPH, Healthcare Economist
- Peter Lopatka, FSA, Actuary
- Jadwiga Najib, PharmD, Drug Utilization Review Expert
- Michael Pasquarella, Pharm D, Pharmacist
- John Powell, Department of Financial Services Delegate
- Casey Quinn, PhD, Healthcare Economist
- Asa Radix, MD, Physician
- Gloria Rodriquez, MD, Physician
- Tara Thomas, RPh, MBA, Pharmacist
- Deborah Wittman, PharmD, Pharmacist
- Jamie Wooldridge, MD, Physician

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Department of Health DUR Board Support Staff

- Amir Bassiri
- Tracy Berger
- Robert Correia
- Kimberly Leonard
- Anthony Merola
- Natalie Ruggiero
- Jacqueline Sexton
- Monica Toohey

V. Summary of DUR Board Activities

The DUR Board held meetings on the following dates during the reporting period:

- November 18, 2021
- May 12, 2022
- July 14, 2022

November 18, 2021

Meeting Agenda for November 18, 2021

The DUR Board reviewed the utilization of the central nervous system (CNS) stimulant use concurrently with other controlled substances, specifically, benzodiazepines and opioids.

The DUR Board was provided updates on the following topics: Statewide Formulary for Opioid Dependence Agents and Opioid Antagonists, Respiratory Syncytial Virus (RSV) season and palivizumab, Direct Acting Antivirals (DAA) for Hepatitis C Virus (HCV), and Supplemental Rebate Initiatives.

Meeting Summary for November 18, 2021

May 12, 2022

Meeting Agenda for May 12, 2022

The DUR Board reviewed information regarding esketamine nasal spray (Spravato®) and recommended clinical criteria to ensure appropriate drug utilization.

The DUR Board reviewed clinical and financial information for ten therapeutic classes subject to the Preferred Drug Program and recommended preferred or non-preferred status.

The DUR Board was presented information regarding asthma guidelines and use of inhaled corticosteroids/long-acting beta agonist combinations for maintenance and reliever therapy.

Meeting Summary for May 12, 2022

July 14, 2022

Meeting Agenda for July 14, 2022

The DUR Board was presented information regarding the management of physician/practitioner administered drugs (PADs).

The DUR Board reviewed clinical and financial information for five therapeutic classes subject to the Preferred Drug Program and recommended preferred or non-preferred status.

The DUR Board reviewed two drugs and two drug classes subject to the Clinical Drug Review Program and recommended changes to the clinical criteria or other drug utilization review interventions to ensure appropriate utilization.

Meeting Summary for July 14, 2022

New RetroDUR criteria (e.g., drug interactions, diagnosis alerts, contraindications, therapeutic appropriateness, overutilization, underutilization, adherence, etc.) for the list of drugs below was vetted through DUR Board:

Month	Drugs
October 2021	selpercatinib, risperidone subQ, cyclobenzaprine ER, pexidartinib, ponatinib, sunitinib, Osimertinib, pazopanib, pemigatinib, relugolix, albiglutide, dulaglutide, exenatide, liraglutide, lixisenatide, semaglutide
November 2021	ibrexafungerp, ripretinib, tazemetostat, finerenone,
December 2021	olanzapine/samidorphan, amphetamine XR, relugolix, decitabine/cedazuridine,
January 2022	fenfluramine, budesonide ER, atogepant, tivozanib, tucatinib, vandetanib, zanubrutinib, cabozantinib
February 2022	selinexor, fostemsavir, trifluridine/tipiracil,
March 2022	romosozumab-aqqg, selumetinib, zanubrutinib
April 2022	glycopyrrolate ODT, budesonide ER, celecoxib/tramadol, upadacitinib, diazepam nasal spray
May 2022	metoclopramide nasal spray, abaloparatide, baclofen
June 2022	abrocitinib, baclofen oral suspension, dupilumab, lurasidone, mirtazapine
July 2022	daridorexant, tezepelumab-ekko, baclofen oral solution, baricitinib, albiglutide, dulaglutide, exenatide, liraglutide, lixisenatide, semaglutide
August 2022	tirzepatide, belumosudil, benralizumab, afatinib,
September 2022	mobocertinib, relugolix/estradiol/norethindrone, upadacitinib,

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VI. Assessment of ProDUR and RetroDUR Cost Avoidance/Savings

ProDUR cost avoidance/savings was calculated by estimating the number claims not overridden at the pharmacy or altered by the prescriber (using the estimated number of alternations in pharmacy therapy as a baseline^) and multiplying by the average cost per prescription claim. The estimated ProDUR cost avoidance for the reporting period was estimated at $126 million (1.9 million claims x $65.67 average cost per prescription claim). This cost avoidance estimate does not take into consideration subsequent paid claims related to changes in pharmacotherapy resulting from ProDUR alerts and is prior to drug rebate offsets. [1,2] Note: the number of on-line claim warnings issued to pharmacies may include multiple alerts per claim and multiple overrides of the same claim.

RetroDUR estimated cost avoidance/savings was determined by evaluating total drug expenditures and claims for the six months prior to and six months after the intervention/alert letters are mailed. Based on this methodology, the intervention group (i.e., providers sent an intervention/alert letter) had a 9.7% decrease in pharmacy claim costs compared with the 0.9% decrease in the comparison intervention group (i.e., no intervention/alert letter sent). The RetroDUR cost avoidance/savings was estimated at $4.8 million prior to drug rebate offsets. [3]

The total DUR Program (ProDUR and RetroDUR) cost avoidance/savings is estimated at $130.8 million. Total FFS pharmacy expenditures (prior to drug rebate offsets) for the reporting period was $748 million.[2] The estimated DUR cost avoidance/savings therefore represents approximately 17.5% of the total pharmacy spend (prior to drug rebate offsets).

VII. FFS Pharmacy Program Enhancements

The Medicaid Program underwent additional changes and updates to the Program as follows:

- Effective April 1, 2022, for New York State (NYS) Medicaid began reimbursing providers for pediatric vaccine counseling visits as part of the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program when provided to Medicaid members ages 18 years of age or younger. Vaccine counseling visits align with the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP).

- CMS has authorized the State of New York to enter into outcomes-based contract arrangements with drug manufacturers for drugs provided to Medicaid beneficiaries. These contracts will be executed on the contract template titled 'Outcome-Based Supplemental Rebate Agreement' submitted to CMS and authorized for use beginning April 1, 2022.

- As part of an administrative budget initiative, uniform clinical standards for coverage of Physician/Practitioner-Administered Drugs (PADs) are being developed to modernize the process for the review of drugs covered under the medical benefit. Clinical criteria for PADs may be established through actions of the DUR board and subsequent approval by the Commissioner of Health.
  Management of Physician/Practitioner-Administered Drugs (PADs)

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- A Single Statewide Medication Assisted Treatment (MAT) Formulary was implemented on October 1, 2021, in accordance with §367-a (7)(e) of Social Services Law. The Single Statewide MAT Formulary aligns coverage parameters across New York State (NYS) Medicaid fee-for-service (FFS) and Medicaid Managed Care (MMC).

- On December 22, 2021, Governor Hochul signed Chapter 720 of the Laws of 2021, which amends Social Services Law and the Public Health Law, in relation to medication for the treatment of substance use disorders. Effective March 22, 2022, prior authorization (PA) will not be required for medications used for the treatment of substance use disorder prescribed according to generally accepted national professional guidelines for the treatment of a substance use disorder. Prescriptions written outside of accepted guidelines may be subject to prior authorization.
  New York State Medicaid Update February 2022 Volume 38 Number 2 (ny.gov)

- Effective September 22, 2022, the New York State (NYS) Medicaid fee-for-service (FFS) professional dispensing fee changed from $10.08 to $10.18 for covered outpatient drugs, when applicable. The NYS Department of Health (DOH) amended this fee to comply with the one percent across-the-board (ATB) Medicaid rate increase, which was based on the enacted budget and was effectuated by the Centers for Medicare and Medicaid Services (CMS) NYS Plan approval.
  New York State Medicaid Update September 2022 Volume 38 Number 10 (ny.gov)

VIII. FFS Pharmacy Program and COVID-19

- Effective December 1, 2021, the New York State Medicaid program began reimbursing pharmacists for COVID-19 vaccination counseling to encourage administration of the COVID-19 vaccine.
  Updated COVID-19 Vaccine Counseling Coverage

- Effective December 13, 2021, NYS Medicaid began covering the dispensing of over-the-counter (OTC) COVID-19 test kits that provide at-home results.
  COVID-19 Guidance for Medicaid Providers

IX. Future Enhancements

Beginning April 1, 2023, NYS Medicaid members enrolled in mainstream Medicaid Managed Care (MMC) plans, Health and Recovery Plans (HARPs), and HIV Special Needs Plans (HIV-SNPs) will receive their pharmacy benefits through NYRx, the Medicaid Pharmacy Program instead of through their MMC plan. Transitioning the pharmacy benefit allows the state to pay pharmacies directly for the drugs and supplies dispensed to Medicaid members. Transitioning the pharmacy benefit from MMC to NYRx will provide NYS with full visibility into prescription drug costs, allow centralization of the benefit, leverage negotiation power, and provide a uniform list of covered drugs with standardized utilization management protocols simplifying and streamlining the drug benefit for NYS Medicaid members. Medicaid members have comprehensive drug coverage and equitable access to an extensive network of over 5,000 pharmacy providers. The pharmacy benefit transition to NYRx ***does not*** apply to NYS Medicaid

members enrolled in Managed Long-Term Care (MLTC) Plans [e.g., MLTC, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Advantage Plus (MAP), the Essential Plan, or Child Health Plus (CHP)].

The DUR Program continues to innovate practices including the development of a physician/practitioner administered drug (PAD) management program and the transition of the pharmacy benefit for managed care members into the NYRx program.

The DUR Program continues to protect and improve the health of New York State Medicaid members. The Department will continue to enhance the ProDUR and RetroDUR Programs and work cooperatively with the DUR Board to develop and implement medication management processes that improve patient outcomes and reduce unnecessary medication costs.

X. Conclusion

The DUR Program has proven to be an asset in the efforts of New York State Medicaid to protect and improve the health of Medicaid members. The Department of Health will continue to work cooperatively with the DUR Board to develop and implement medication management processes that improve patient outcomes and reduce unnecessary medication costs.

XI. References/Sources

[1] DOH EmedNY, Mobius Report (CR50028-R0119) for 10/01/2021 to 09/30/2022

[2] SUNY, CMS Annual Report FFY2022 20230417 Report for 10/01/2021 to 9/30/2022

[3] Kepro, NY RDUR Estimated Cost Savings Report (ATT4-2022-NY-CSCAM)

[4] Kepro, Retrospective Educational Outreach Summary Report (SUM1-2022-NY-REOS)

[5] SUPPORT for Patients and Communities Act

[6] Preferred Drug and Clinical Drug Review Programs

Social Services (SOS) Chapter 55, Article 5, Title 11-C, Section 369-BB, DUR Board