



**Department
of Health**

Statewide Formulary for Opioid Dependence Agents and Opioid Antagonists

All Stakeholder: Implementation Update

August 31, 2021

Overview

- Implementation Overview
- Formulary Structure and Standard Clinical Criteria
- Implementation Impacts: FFS and Managed Care
- Communications & Resources
- Q&A

Implementation Overview

Implementation Overview

Effective October 1, 2021, per the enacted New York State Executive Budget for State Fiscal Year 2020-2021 and in accordance with § 367-a (7) (e) of Social Services Law, the Department of Health (DOH) is implementing a single statewide formulary for Opioid Antagonists and Opioid Dependence Agents for [Medicaid Managed Care Plans](#) and Medicaid Fee for Service (FFS).

Under the statewide formulary, Medicaid FFS and Medicaid Managed Care (MC) will:

- follow a single formulary, where Prior Authorization (PA) and coverage parameters are consistent across the Medicaid Program, preferred products are available without PA (unless coverage parameters are exceeded) and non-preferred products require PA and;
- use standard clinical criteria for approval of a non-preferred drug in accordance with § 273 (3) (a) of Public Health Law.

Implementation Guiding Principles

- Ensure members are provided with continued access to needed medications used to treat substance use disorder with minimal impact.
 - The Statewide MAT Formulary is comprehensive, all drugs remain available.
- Maintain communication with stakeholders (e.g., providers, patient advocates, pharmacy associations, wholesalers, and Managed Care Plans)
- Establish project management infrastructure and resources to ensure program and operational readiness.
- Utilize “post implementation” processes that ensure appropriate oversight, issue identification, tracking and resolution.

Formulary Structure and Criteria

Percent of Drug on Formulary

	% on Formulary		
	Count of Product Formulations & Strengths	FFS	MCO Plan Average
OPIOID ANTAGONISTS	4	100%	94%
NALOXONE HCL INJ	1	100%	88%
NALOXONE HCL SPRAY	1	100%	100%
NALOXONE HCL SYRINGE	1	100%	88%
NALTREXONE HCL TAB	1	100%	100%
OPIOID DEPENDENCE AGENTS INJECTABLE	2	100%	63%
BUPRENORPHENE ER INJ	1	100%	25%
NALTREXONE ER INJ	1	100%	100%
OPIOID DEPENDENCE AGENTS – ORAL/TRANSMUCOSAL	16	100%	57%
BUPRENORPHINE HCL (TAB)	2	100%	94%
BUPRENORPHINE HCL/NALOXONE HCL (TAB/FILM)	14	100%	52%
Grand Total	22	100%	64%

Formulary Structure and Criteria

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Opioid Antagonists		
Naloxone (syringe, vial) Naltrexone Narcan [®] (nasal spray)	None	None
Opioid Dependence Agents - Injectable		
Vivitrol [®] Sublocade [™]	None	None

Formulary Structure and Criteria

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Opioid Dependence Agents – Oral/Transmucosal ^{CC, F/Q/D}		
Buprenorphine	Bunavail [®]	<p>CLINICAL CRITERIA (CC)</p> <ul style="list-style-type: none"> PA required for initiation of opioid therapy for patients on established opioid dependence therapy <p>QUANTITY LIMIT:</p> <ul style="list-style-type: none"> buprenorphine sublingual (SL): Six tablets dispensed as a 2-day supply; not to exceed 24 mg per day buprenorphine/ naloxone tablet and film (Bunavail[™], Suboxone[®], Zubsolv[®] up to 5.7 mg/1.4 mg strength): Three sublingual tablets or films per day; maximum of 90 tablets or films dispensed as a 30-day supply, not to exceed 24 mg-6 mg of Suboxone, or its equivalent per day buprenorphine/naloxone tablet (Zubsolv[®] 8.6 mg/2.1 mg strength): Maximum of 60 tablets dispensed as a 30-day supply buprenorphine/naloxone tablet (Zubsolv[®] 11.4 mg/2.9 mg strength): Maximum of 30 tablets dispensed as a 30-day supply
Suboxone [®] BLTG	buprenorphine/ naloxone film	
buprenorphine/ naloxone tablet	Zubsolv [®]	

Key Implementation Takeaway's

- Patient access to medications used to treat substance use disorder will not change as a result of this initiative and will remain the same, and in many cases improve because of the alignment of the formulary across FFS and MC.
- Coverage parameters for Opioid Antagonists and Opioid Dependence Agents will become consistent across the Medicaid Program.
- All Opioid Antagonists and Opioid Dependence Agents have preferred products on formulary which will not be subject to prior authorization when prescribed consistent with FDA labeling.
- All agents are subject to FDA approved quantity/frequency/duration limits.
- Pharmacies will have adequate stock and are prepared for implementation.



Statewide Formulary for Opioid Dependence Agents and Opioid Antagonists

Impacted Stakeholders



Patients

- Continue to present Medicaid benefit card or Plan benefit card to pharmacies in order to access medications
- Continued access to needed medications to treat substance use disorder
- Pharmacists will substitute and provide counseling on the change from generic buprenorphine/naloxone film to Suboxone
- Copays will remain the same



Pharmacies

- Point of Service (POS) messaging will instruct the Pharmacist to switch to Suboxone without prescriber intervention
- Dispense as Written (DAW)/Product Selection Code of '1' is not required
- Patients on generic buprenorphine/naloxone film will not require a new prescription when switching to brand Suboxone
- Pharmacists will continue to have the ability to request an emergency supply, if needed, if there is a delay in obtaining PA



Prescribers

- Follow a single statewide formulary in which PA/coverage parameters are consistent across the Medicaid Program (FFS & MC)
- PA is only required if the product is non-preferred or exceeds FDA labeling
- PA process has a 24-hour turnaround timeframe once all required information is submitted by the prescriber.
- Prescribers will continue to have the ability to request emergency supply, if needed, if there is a delay in obtaining PA



NY State Medicaid

- Provide oversight and policy guidance to the MCO's to ensure alignment of the single statewide formulary and PA/coverage parameters for Opioid Antagonists and Opioid Dependence Agents
- Maintain open communication with Managed Care Plans and monitor post-implementation
- Maintain communication with Pharmacies to ensure adequate stock of Suboxone & member access to medications



Managed Care Plans

- Per legislation the MCOs must follow the single statewide formulary and PA/coverage parameters for Opioid Antagonists and Opioid Dependence Agents
- Per legislation the MCOs must continue alignment of the 24-hr turnaround timeframe for PA, once all required information is submitted by the prescriber, as well as continue to allow emergency supply requests from the prescriber or pharmacy

Communications and Resources

Communications



- A Medicaid Update article for August 2021 will be published in early September with guidance on:
 - Implementation
 - Formulary Structure and Criteria
 - Medicaid Managed Care Billing for Pharmacies
 - FFS Billing for Pharmacies
 - Additional Resources
- Individual Managed Care Websites will be updated with implementation information in early September

Resources



DOH Medicaid Update:

https://www.health.ny.gov/health_care/medicaid/program/update/main.htm



MRT LISTSERV:

https://health.ny.gov/health_care/medicaid/redesign/listserv.htm



Single Statewide Medication Assisted Treatment (MAT) Formulary website:

<https://newyork.fhsc.com/providers/mat.asp>



FFS Preferred Drug List:

https://newyork.fhsc.com/downloads/providers/NYRx_PDP_PDL.pdf



Managed Care Information:

<https://mmcdruginformation.nysdoh.suny.edu/>

Questions & Answers

Frequently Asked Questions

Question 1: Will I continue to receive my buprenorphine/naloxone (generic suboxone) medication?

Yes. You will continue to receive this medication but in the form of the branded product (Suboxone).

Question 2: Do patients who are on generic Suboxone need a new prescription?

No.

Question 3: Will PA be required for preferred/formulary drugs?

Only if prescribed outside of FDA approved frequency/quantity/duration limits, as required by Federal law.

Question 4: What happens if I want to use the non-preferred product and don't want to switch to the preferred product?

Your doctor will need to obtain a prior authorization however, all products remain available.

Question 5: If I need a PA how long will that process take?

Once all relevant information is received from the prescriber, a determination will be made within 24 hours. If there is a delay in obtaining the relevant information or an emergency situation exists, the pharmacist or prescriber may request a 5-day emergency supply by contacting the insurer.

Question 6: Will Sublocade be available as a pharmacy benefit?

Yes.

Questions?

*Please submit your question to
All Panelists using the Q&A feature of
the WebEx Event meeting.*

