



**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
<b>OPIOID ANTAGONISTS</b>	<b>4</b>	<b>100%</b>	<b>94%</b>
NALOXONE HCL INJ	1	100%	88%
NALOXONE HCL SPRAY	1	100%	100%
NALOXONE HCL SYRINGE	1	100%	88%
NALTREXONE HCL TAB	1	100%	100%
<b>OPIOID DEPENDENCE AGENTS INJECTABLE</b>	<b>2</b>	<b>100%</b>	<b>63%</b>
BUPRENORPHENE ER INJ	1	100%	25%
NALTREXONE ER INJ	1	100%	100%
<b>OPIOID DEPENDENCE AGENTS – ORAL/TRANSMUCOSAL</b>	<b>16</b>	<b>100%</b>	<b>57%</b>
BUPRENORPHINE HCL (TAB)	2	100%	94%
BUPRENORPHINE HCL/NALOXONE HCL (TAB/FILM)	14	100%	52%
<b>Grand Total</b>	<b>22</b>	<b>100%</b>	<b>64%</b>

# Formulary Structure and Criteria

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



# Formulary Structure and Criteria

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

# Key Implementation Takeaway's

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- 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.



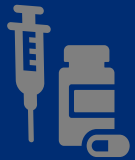
# Statewide Formulary for Opioid Dependence Agents and Opioid Antagonists

## 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

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- 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](https://www.health.ny.gov/health_care/medicaid/program/update/main.htm)



MRT LISTSERV:

[https://health.ny.gov/health\\_care/medicaid/redesign/listserv.htm](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](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.*

