Buprenorphine, Buprenorphine/Naloxone for Opioid Dependence Quantity Limit Program Summary

Quantity limits apply to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
03-01-2024	12-01-2016

FDA APPROVED INDICATIONS AND DOSAGE

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	Buprenorphine HCl SL Tab 2 MG (Base Equiv)	2 MG	6	Tablets	90	DAYS	Quantity limit per 90 days is to allow for a single course of induction treatment		
	Buprenorphine HCl SL Tab 8 MG (Base Equiv)	8 MG	6	Tablets	90	DAYS	Quantity limit per 90 days is to allow for a single course of induction treatment		
	Buprenorphine HCl-Naloxone HCl SL Tab 2-0.5 MG (Base Equiv)	2-0.5 MG	120	Tablets	30	DAYS			
	Buprenorphine HCl-Naloxone HCl SL Tab 8-2 MG (Base Equiv)	8-2 MG	90	Tablets	30	DAYS			
Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 12-3 MG (Base Equiv)	12-3 MG	60	Films	30	DAYS			
Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 2-0.5 MG (Base Equiv)	2-0.5 MG	120	Films	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 4-1 MG (Base Equiv)	4-1 MG	60	Films	30	DAYS			
Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 8-2 MG (Base Equiv)	8-2 MG	60	Films	30	DAYS			
Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 0.7-0.18 MG (Base Eq)	0.7-0.18 MG	30	Tablets	30	DAYS			
Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 1.4-0.36 MG (Base Eq)	1.4-0.36 MG	90	Tablets	30	DAYS			
Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 11.4-2.9 MG (Base Eq)	11.4-2.9 MG	30	Tablets	30	DAYS			
Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 2.9-0.71 MG (Base Eq)	2.9-0.71 MG	30	Tablets	30	DAYS			
Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 5.7-1.4 MG (Base Eq)	5.7-1.4 MG	30	Tablets	30	DAYS			
Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 8.6-2.1 MG (Base Eq)	8.6-2.1 MG	60	Tablets	30	DAYS			

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Buprenorphine HCl SL Tab 2 MG (Base Equiv)	2 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Buprenorphine HCl SL Tab 8 MG (Base Equiv)	8 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Buprenorphine HCl-Naloxone HCl SL Tab 2-0.5 MG (Base Equiv)	2-0.5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Buprenorphine HCl-Naloxone HCl SL Tab 8-2 MG (Base Equiv)	8-2 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 12-3 MG (Base Equiv)	12-3 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 2-0.5 MG (Base Equiv)	2-0.5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 4-1 MG (Base Equiv)	4-1 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 8-2 MG (Base Equiv)	8-2 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 0.7-0.18 MG (Base Eq)	0.7-0.18 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 1.4-0.36 MG (Base Eq)	1.4-0.36 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 11.4-2.9 MG (Base Eq)	11.4-2.9 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 2.9-0.71 MG (Base Eq)	2.9-0.71 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 5.7-1.4 MG (Base Eq)	5.7-1.4 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 8.6-2.1 MG (Base Eq)	8.6-2.1 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. If the requested agent is buprenorphine sublingual tablets, then ONE of the following: 1. The patient is pregnant **OR** 2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to naloxone or naltrexone **OR** B. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** C. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** D. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval:** • Buprenorphine sublingual tablets: Approve for up to 12 months. For increased quantities, the quantity requested up to a maximum dose of 32 mg buprenorphine may be approved. • Buprenorphine/naloxone sublingual tablets and films: Approve for up to 6 months. NOTE: For increased quantities, the quantity requested up to a maximum dose of 32 mg buprenorphine may be approved. • Zubsolv: Approve for up to 6 months NOTE: For increased quantities, the quantity requested up to a maximum dose of 22.8 mg buprenorphine may be approved.