

**Sublocade
Probuphine
Effective 10/01/19**

Plan	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	Sublocade does NOT require a prior authorization for MassHealth		

Overview

Sublocade is an extended-release injection for treatment of moderate to severe opioid use disorder in patients who have initiated treatment with 8 to 24 mg of a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.

Probuphine is a subdermal implant for maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low to moderate doses of a transmucosal buprenorphine-containing product for 3 months or longer with no need for supplemental dosing or adjustments.

Coverage Guidelines

Approval of Sublocade and Probuphine will be granted if the member meets the following drug specific criteria:

Sublocade

1. Member has diagnosis of moderate to severe opioid use disorder **AND**
2. Member has been stabilized on ≤ 24 mg buprenorphine per day for at least seven days; **AND**
3. Provider has submitted medical necessity for the use of the extended-release injection formulation due to one of the following:
 - a. The member has been stable on transmucosal buprenorphine therapy delivering an equivalent of 8 to 24 mg of daily buprenorphine for at least seven days **AND** significant patient safety concerns that would make having transmucosal buprenorphine containing products in the home not ideal **OR**



- b. The member has been stable on transmucosal buprenorphine therapy delivering an equivalent of 8 to 24 mg of daily buprenorphine for at least seven days AND significant concerns with diversion of transmucosal buprenorphine-containing buprenorphine products exists

Probuphine

1. Member has diagnosis of moderate to severe opioid use disorder
2. Documentation the member is currently maintained on a dose of 8 mg/day or less of a transmucosal buprenorphine product equivalent (See Appendix A) AND
3. Documentation the member has been stable on transmucosal buprenorphine or equivalent product, for three months or longer without requiring supplemental dosing or adjustments for 6 months.
4. Provider has submitted medical records documenting an adverse allergic reaction, or cannot be expected or managed during the course of buprenorphine therapy, contraindication or inadequate response to all other appropriate therapeutic alternatives

Continuation of Therapy

Sublocade

Requests for continuation of therapy will require all the following documentation:

1. The member will not receive supplemental transmucosal buprenorphine-containing products while receiving Sublocade (buprenorphine extended-release)

Probuphine

Requests for a second six-month implant of Probuphine may be authorized if all the following criteria are met:

1. Documentation the Member has been stable on Probuphine (buprenorphine) for six months without requiring supplemental transmucosal dosing or dosing adjustments **AND**
2. Documentation the Member has had only one Probuphine (buprenorphine) implant previously.

Limitations

1. **Approvals will be granted for the following:**
 - a. **Sublocade** – 6 months.
 - b. **Probuphine** – One 6 month implant.

Appendix

Dosing equivalent of 8mg per day or less of transmucosal buprenorphine products

DRUG	DOSE
Buprenorphine	8mg or less
Suboxone [or generic equivalent]	8/2 mg or less
Bunavail	4.2/0.7 mg or less
Zubsolv	5.7/1.4 mg or less

References

1. 1. Sublocade (buprenorphine extended-release) [prescribing information]. North Chesterfield, VA: Indivior Inc; March 2018
2. 30. Buprenorphine sublingual tablets [prescribing information]. Morgantown, WV: Mylan; February 2018.



3. 31. Probuphine (buprenorphine) implant for subdermal administration [prescribing information]. Princeton, NJ: Braeburn Pharmaceuticals, Inc.; February 2018
4. Suboxone sublingual film (buprenorphine/naloxone) [prescribing information]. Richmond, VA: Indivior; February 2018.
5. Zubsolv (buprenorphine/naloxone) [prescribing information]. Morristown, NJ: Orexo US; February 2018.
6. Bunavail (buprenorphine/naloxone) [prescribing information]. Raleigh, NC: BioDelivery Sciences International Inc; February 2018

Review History

02/20/19 – Reviewed

11/18/20 – Reviewed P&T

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