



**Bunavail buccal film
Suboxone (buprenorphine/naloxone film)
Zubsolv sublingual tablets
Effective 10/1/2022**

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
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	N/A		

Overview

Buprenorphine/naloxone tablets (Suboxone), Zubsolv (buprenorphine/naloxone tablet), Bunavail (buprenorphine/naloxone buccal film) contain buprenorphine, a partial opioid agonist, and naloxone, an opioid antagonist, indicated for the maintenance treatment of opioid dependence.

Coverage Guidelines

Authorization may be granted for members when the following criteria is met, and documentation is provided:

1. Member has a diagnosis of opioid dependence **AND**
2. Member has had a documented inadequate response or intolerance with the generic buprenorphine/naloxone tablets or buprenorphine sublingual tablet

Authorization may be granted for approval over the quantity limit if the member meets the following criteria:

1. The member’s dose of buprenorphine/naloxone being tapered down to allow 30mg or less per day **OR**
2. Prior attempts have been made to titrate the member down to 90 tablets per 30 days and the member has relapsed

Note: Recommended dosing is 16mg/4mg of Suboxone daily. Clinical studies have shown that 16mg/4mg of Suboxone is a clinically effective dose compared with placebo and indicate that doses as low as 12mg/3mg may be effective in some patients. The dosage of Suboxone should be adjusted in increments/decrements of 2mg/0.5mg or 4mg/1mg to a level that holds the patient in treatment and



suppresses opioid withdrawal effects. This is likely to be in the range of 4mg/1mg to 24mg/6mg per day depending on the individual. The recommended target dosage of Suboxone film during maintenance is 16 mg/4 mg buprenorphine/naloxone/day as a single daily dose. Dosages higher than 24 mg/6 mg daily have not been demonstrated to provide a clinical advantage.

Note: Bunavail buccal film is indicated for maintenance treatment. The recommended target dosage of Bunavail buccal film is 8.4/1.4 mg per day as a single daily dose. Bunavail should be adjusted in increments/decrements of 2.1/0.3 mg to a level that holds the patient in treatment and suppresses opioid withdrawal signs and symptoms. The maintenance dose of Bunavail buccal film is generally in the range of 2.1/0.3 mg to 12.6/2.1 mg per day depending on the individual patient. Dosages higher than this have not been demonstrated to provide any clinical advantage.

Continuation of Therapy

Reauthorization requires physician documentation of stability and effectiveness of treatment plan.

Please note: buprenorphine tablets and buprenorphine/naloxone tablets are available without prior authorization within their quantity limits.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.
2. Authorizations for quantities exceeding the limit will be granted for 6 months.
3. The following quantity limits apply:

Suboxone® (buprenorphine/naloxone film): 2 mg/0.5 mg	90 films per 30 days
Suboxone® (buprenorphine/naloxone film): 8 mg/2 mg	120 films per 30 days
Suboxone® (buprenorphine/naloxone film): 4 mg/1 mg, 12 mg/3 mg	60 films per 30 days
Zubsolv® (buprenorphine/naloxone tablet) 11.4 mg/2.9mg	30 tablets per 30 days
Zubsolv® (buprenorphine/naloxone tablet): 0.7 mg/0.18 mg, 1.4 mg/0.36 mg, 2.9 mg/0.71 mg, 5.7 mg/1.4 mg, 8.6 mg/2.1 mg	60 tablets per 30 days
Bunavail® (buprenorphine/naloxone buccal film)	60 films per 30 days
buprenorphine/naloxone sublingual tablets: 2 mg/0.5 mg	90 tablets per 30 days
buprenorphine/naloxone sublingual tablets: 8 mg/2 mg	120 tablets per 30 days

References

1. Bunavail (buprenorphine and naloxone) [prescribing information]. Raleigh, NC: BioDelivery Sciences International Inc; February 2018.
2. Buprenorphine HCl/Naloxone HCl Sublingual Tablets [prescribing information]. Eatontown, NJ: West-Ward; February 2018
3. Suboxone sublingual film (buprenorphine/naloxone) [prescribing information]. Richmond, VA: Indivior; February 2018.
4. Suboxone sublingual tablet (buprenorphine/naloxone) [prescribing information]. Richmond, VA: Indivior; February 2018
5. Zubsolv (buprenorphine and naloxone) [prescribing information]. Morristown, NJ: Orexo US; February 2018

**Review History**

04/23/18 – Reviewed

04/17/19 – Reviewed

07/20/22 – Reviewed and updated for July P&T. Consolidated QL criteria with PA criteria. Effective 10/1/22.

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