

**Bunavail buccal film**  
**Suboxone (buprenorphine/naloxone film)**  
**Zubsolv sublingual tablets**  
**Effective 02/01/2023**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical Benefit</b> Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
<b>Exceptions</b>	N/A		

### Overview

Suboxone (buprenorphine/naloxone tablets), 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 and films 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

### **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.

11/16/2022 – Reviewed and Updated for Nov P&T; removed generic buprenorphine tablets and films from PA criteria. These items will continue to have PA. Added a note that states buprenorphine tablets and buprenorphine/naloxone tablets and films are available without prior authorization within their quantity limits. Effective 02/01/23

