



**Suboxone, Zubsolv, & Bunavail Quantity Limit
Effective April 25, 2016**

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|------------------------------|--|---------------------|---|
| Plan | <input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange | Program Type | <input 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

N/A

Coverage Guidelines

| DRUG | QUANTITY PER 30 DAYS |
|---|---|
| buprenorphine/naloxone sublingual <u>tablets</u> | <ul style="list-style-type: none"> • 90 tablets of 2mg/0.5mg • 90 tablets of 8mg/2mg |
| Suboxone® (buprenorphine/naloxone) <u>sublingual film</u> | <ul style="list-style-type: none"> • 90 SL films of 2mg/0.5mg • 60 SL films of 4mg/1mg • 90 SL films of 8mg/2mg • 60 SL films of 12mg/3mg |
| Zubsolv® (buprenorphine/naloxone) sublingual <u>tablets</u> | <ul style="list-style-type: none"> • 60 tablets of 1.4mg/0.36mg • 60 tablets of 5.7mg/1.4mg • 60 tablets of 8.6mg/2.1mg |
| Bunavail® (buprenorphine/naloxone) <u>buccal film</u> | <ul style="list-style-type: none"> • 30 units of 2.1mg/0.3mg film • 90 units of 4.2mg/0.7mg film • 30 units of 6.3mg/1.0mg film |

AllWays Health Partners may approve 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.

Limitations

1. Approvals will be granted for 6 months

References

1. Suboxone sublingual film [package insert]. Richmond (VA): Reckitt Benckiser Pharmaceuticals, Inc.; 2014 Apr.
2. Buprenorphine HCl and naloxone HCl sublingual tablet [package insert]. Hauppauge (NY: Amneal Pharmaceuticals of NY; 2015 Feb.
3. Zubsolv [package insert]. Wilmington (NC): Orexo US, Inc.; 2014 Dec.
4. Bunavail® [package insert]. Raleigh (NC): BioDelivery Sciences International Inc.; 2014 Jun.

Review History

04/25/16 – Reviewed

Disclaimer

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