BlueCross BlueShield of North Carolina

BUPRENORPHINE/NALOXONE (Bunavail™, Suboxone®, Zubsolv®)

BUPRENORPHINE (Subutex®)

UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS: Opioid Dependence

BRAND (generic) NAMES:

Bunavail (buprenorphine/naloxone) buccal films
2.1mg/0.3mg, 4.2mg/0.7mg, 6.3mg/1mg

Suboxone (buprenorphine/naloxone) sublingual (SL) films
2mg/0.5mg, 4mg/1mg, 8mg/2mg, 12mg/3mg

buprenorphine/naloxone (Suboxone) sublingual (SL) tablets
2mg/0.5mg, 8mg/2mg

buprenorphine (Subutex) SL tablets
2mg, 8mg

Zubsolv (buprenorphine/naloxone) sublingual (SL) tablets
1.4mg/0.36mg, 2.9mg/0.71mg, 5.7mg/1.4mg, 8.6mg/2.1mg, 11.4mg/2.9mg

FDA-APPROVED INDICATIONS: Treatment of opioid dependence.

COVERAGE AUTHORIZATION CRITERIA

Suboxone, buprenorphine (Subutex), Zubsolv, or Bunavail is covered when **ALL** of the following conditions are met:

1. The prescriber meets the qualification certification criteria in the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is a qualified physician under the DATA to prescribe Subutex, Suboxone, Zubsolv, and Bunavail; **AND**
2. The patient has a diagnosis of opioid dependence; **AND**
3. The patient is 16 years of age or older; **AND**
4. The patient is abstinent from illicit drug use (including problematic alcohol and/or benzodiazepine use); **AND**
5. The patient has a psychosocial treatment plan and is compliant with all elements of the treatment plan including:

a) recovery-oriented activities
b) psychotherapy, and/or
c) other psychosocial modalities; **AND**

6. If buprenorphine (Subutex) SL tablets are being requested:
   a) The patient must meet the above criteria (1-5); **AND**
   b) The treatment is being used for induction therapy (if approved, it will be approved for 5 days); **OR**
   c) The patient has a medical record documentation of an allergy to naloxone or naltrexone; **OR**
   d) The patient is pregnant and has medical record documentation of a treatment plan.
7. If Zubsolv or Bunavail is requested, the patient must have tried and failed, be intolerant to, or has a contraindication to generic buprenorphine/naloxone SL tablets.

AND ONE of the following:

8. The quantity requested is less than or equal to the program quantity limit (see below); **OR**
9. The quantity (dose) requested is within FDA-approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength; **OR**
10. The quantity (dose) requested is greater than the maximum dose recommended in FDA-approved labeling, when specified, or to the safest studied dose per the manufacturer's product insert and the prescriber has submitted documentation in support of therapy with a higher dose or longer duration for the intended diagnosis.

QUANTITY LIMITS

Medication Name/Strength	Quantity Limit per Day
Suboxone sublingual film	
2mg/0.5mg	3 films per day
4mg/1mg	
8mg/2mg	
12mg/3mg	2 films per day
buprenorphine/naloxone (Suboxone) sublingual tablets	
2mg/0.5mg	3 tablets per day
8mg/2mg	
buprenorphine (Subutex) sublingual tablets	
2mg	3 tablets per day
8mg	
Zubsolv sublingual tablets	
1.4mg/0.36mg	3 tablet per day
5.7mg/1.4mg	
2.9mg/0.71mg, 8.6mg/2.1mg	2 tablet per day
11.4mg/2.9mg	1 tablet per day
Bunavail buccal film	
2.1mg/0.3mg	3 films per day
4.2mg/0.7mg	
6.3mg/1mg	2 films per day

Length of Approval:
buprenorphine (Subutex): up to 5 days for induction therapy or, based on submitted information, for up to 12 months

Suboxone, Zubsolv, or Bunavail: up to 12 months

WARNINGS AND PRECAUTIONS

- Buprenorphine can be abused in a similar manner to other opioids. Clinical monitoring appropriate to the patient's level of stability is essential. Multiple refills should not be prescribed early in treatment or without appropriate patient follow-up visits.
- Significant respiratory depression and death have occurred in association with buprenorphine, particularly when taken by the intravenous (IV) route in combination with benzodiazepines or other CNS depressants (including alcohol).
- Consider dose reduction of CNS depressants, buprenorphine/naloxone or buprenorphine, or both in situations of concomitant prescription.
- Store buprenorphine/naloxone or buprenorphine products safely out of the sight and reach of children. Buprenorphine can cause severe, possibly fatal, respiratory depression in children.
- Chronic administration produces opioid-type physical dependence. Abrupt discontinuation or rapid dose taper may result in opioid withdrawal syndrome.
- Monitor liver function tests prior to initiation and during treatment and evaluate suspected hepatic events.
- Do not administer buprenorphine/naloxone or buprenorphine products to patients with known hypersensitivity to buprenorphine or naloxone.
- A marked and intense opioid withdrawal syndrome is highly likely to occur with parenteral misuse of buprenorphine/naloxone by individuals physically dependent on full opioid agonists or by sublingual administration before the agonist effects of other opioids have subsided.
- Neonatal withdrawal has been reported following use of buprenorphine by the mother during pregnancy.
- Buprenorphine/naloxone or buprenorphine is not appropriate as an analgesic. There have been reported deaths of opioid naïve individuals who received smaller doses of buprenorphine.
- Caution patients about the risk of driving or operating hazardous machinery.

DOSAGE AND ADMINISTRATION:
Administer as a single daily dose.

Suboxone: The recommended daily dose for maintenance treatment is 16mg/4mg buprenorphine and naloxone.

Zubsolv: The recommended daily dose for maintenance treatment is 11.4mg/2.8mg buprenorphine and naloxone.

SUBOXONE sublingual tablet dosage strength	Corresponding ZUBSOLV dosage strength
One 2 mg/0.5 mg buprenorphine/naloxone sublingual tablet	One 1.4 mg/0.36 mg ZUBSOLV sublingual tablet
4 mg/1 mg buprenorphine/naloxone taken as: • Two 2 mg/0.5 mg sublingual buprenorphine/naloxone tablets	One 2.9 mg/0.71 mg ZUBSOLV sublingual tablet
One 8 mg/2 mg buprenorphine/naloxone sublingual tablet	One 5.7 mg/1.4 mg ZUBSOLV sublingual tablet
12 mg/3 mg buprenorphine/naloxone, taken as: • One 8 mg/2 mg sublingual buprenorphine/naloxone tablet AND • Two 2 mg/0.5 mg sublingual buprenorphine/naloxone tablets	One 8.6 mg/2.1 mg ZUBSOLV sublingual tablet
16 mg/4 mg buprenorphine/naloxone, taken as: • Two 8 mg/2 mg sublingual buprenorphine/naloxone tablets	One 11.4 mg/2.9 mg ZUBSOLV sublingual tablet

Bunavail: The recommended daily dose for maintenance treatment is 8.4 mg/1.4 mg buprenorphine and naloxone.

SUBOXONE sublingual tablet dosage strength	Corresponding BUNAVAIL dosage strength
4 mg/1 mg buprenorphine/naloxone	2.1 mg/0.3 mg buprenorphine/naloxone
8 mg/2 mg buprenorphine/naloxone	4.2 mg/0.7 mg buprenorphine/naloxone
12 mg/3 mg buprenorphine/naloxone	6.3 mg/1 mg buprenorphine/naloxone

REFERENCES:

1. Bunavail prescribing information. BioDelivery Sciences International, Inc. June 2014.
2. Drug Addiction Treatment Act of 2000. http://buprenorphine.samhsa.gov/fulllaw.html. Accessed 12 Sept 2012.
3. Suboxone prescribing information. http://www.suboxone.com/pdfs/SuboxonePI.pdf . August 2012.
4. Subutex prescribing information. http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020732s006s007lbl.pdf. December 2011.
5. Zubsolv prescribing information. http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204242s000lbl.pdf. July 2013.

POLICY IMPLEMENTATION/UPDATE INFORMATION

September 2016: Added new strengths (2.9 mg/0.71 mg, 11.4 mg/2.9 mg) of Zubsolv to the criteria.