

Pharmacy Policy Bulletin

Category:	Managed Rx Coverage
Number:	J-23
Subject:	Subutex® (buprenorphine) and Suboxone® (buprenorphine and naloxone)
Effective Date Begin:	December 3, 2008
Effective Date End:	
Original Date:	June 4, 2003
Review Date(s):	December 2, 2009 December 3, 2008 December 5, 2007 September 5, 2007 May 16, 2007 May 17, 2006 May 18, 2005 May 19, 2004

Policy Applies to: *Commercial and Medicare plans*

This policy only applies to prescription drug benefits for those members who have coverage for substance abuse as part of their benefits program that is administered through Highmark Blue Shield.

Background:

Subutex® (buprenorphine) and Suboxone® (buprenorphine and naloxone) sublingual tablets are classified as schedule III controlled substances indicated for the treatment of opioid dependence. Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa opioid receptor while naloxone is an antagonist at the mu-opioid receptor. Buprenorphine is used as a single agent for the initial treatment (induction) of opioid dependence and the combination product is used following the initial phase of therapy. The combination product (Suboxone®) is preferred for unsupervised use because the naloxone component limits its abuse potential. If it is misused parenterally, the naloxone will produce withdrawal symptoms, often intense, in patients dependent on other opioid agonists. Patients should be titrated to effectiveness as quickly as possible while on buprenorphine alone. This is based on studies that showed high drop-out rates due to opioid withdrawal when buprenorphine was gradually titrated over several days. Relapse rates for patients with opiate dependence is high, some studies cite relapse rates over 95%. The best chance of attaining long-term success occurs with pharmacological and psychological therapy.

Approval Criteria:

Subutex:

When a benefit covers substance abuse, Subutex® will be covered for a 5 day-supply (160 mg) of medication within the last 90 days for the induction treatment of opioid dependence.

Authorization for an additional coverage period can be approved for female members who are pregnant and require treatment for opioid

Authorization for an additional coverage period can be approved for female members who are pregnant and require treatment for opioid dependence for the duration of their pregnancy (up to 9 months of treatment, at which time the member can be transitioned to treatment with the combination tablet). Otherwise, Subutex® will not be covered for long-term therapy.

Suboxone:

When a benefit, coverage for Suboxone® will be approved if a member meets the following criteria:

- The prescribed dose of Suboxone does not exceed 90 tablets/25 days.

Members who meet the criteria as outlined above will receive automatic authorization at the level of the pharmacy without documentation of additional information. Claims will adjudicate automatically with no prior authorization required.

For members who do not meet the criteria above, the dispensing pharmacist will be prompted that prior authorization is required. Prior authorization criteria include the following:

1. The member is being treated for opioid dependence by a physician certified in addiction medicine AND
2. The patient is enrolled in at least one ancillary service (e.g. psychiatric, counselling, behavioral education) AND
3. The prescribed dose of Suboxone does not exceed 24mg/day

Upon receiving authorization for payment of claims for Suboxone, claims for narcotic pain medications (i.e. opioid containing products) will reject at the point of sale if the member has an active claim for Subutex or Suboxone in their pharmacy claims history. Authorization for coverage of a narcotic pain medication (i.e. opioid) claim will be provided if the member has a documented acute pain condition (e.g. acute traumatic injury) in which treatment with other agents would cause insufficient pain control or if the member requires treatment for pain related to a terminal illness.

If approved, authorization will be granted for a period of up to one year.

References:

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4. Johnson RE, Chutuape M, Strain EC, et al. A comparison of levomethadyl acetate, buprenorphine, and methadone for opioid dependence. *N Engl J Med*. Nov 2004; 343(18):1290-97.
5. Center for Substance Abuse Treatment. Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction. Rockville (MD): Substance Abuse and Mental Health Services Administration; 2004. 171 p. (Treatment improvement protocol; no. TIP 40).
6. Johnson RE, Strain EC, Amass L. Buprenorphine: how to use it right. *Drug and Alcohol Dependence*. 2003; 70:S59-S77

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8. Fudala PJ, Bridge TP, Herbert S, et al. Office-based Treatment of Opiate Addiction with a Sublingual-Tablet Formulation of Buprenorphine and Naloxone. N Engl J Med. Sept 2003; 349: 949-58.
9. Boothby LA, Doering PL. Buprenorphine for the treatment of opioid dependence. Am J Health-Sys Pharm. Feb 2007; 64:266-72.
10. Subutex® (buprenorphine)/Suboxone® (buprenorphine/naloxone) prescribing information. Reckitt Benckiser Pharmaceuticals, Inc. Richmond, VA. June 2005.

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