



Buprenorphine

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Policy

Blue Cross and Blue Shield of Kansas City will provide coverage for buprenorphine products when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

I. Buprenorphine products require authorization and may be considered medically necessary when criteria **A**, **B** and **C** below are met:

A. The product is being used for the treatment of opioid dependence (ICD-9 304.0)

AND

B. The prescriber has a valid Drug Addiction Treatment Act of 2000 (DATA) waiver (See *Appendix*).

AND

C. There is no concurrent opioid use.

II. Quantity Limitations, and Authorization Period

B. Initial authorization: When prior authorized, buprenorphine may be covered in the initial 3 month period in quantities up to 90 tablets or filmstrips per month, not to exceed 24 mg of buprenorphine per day.

C. Continued authorization: After initial approval, authorization shall be reviewed every 6 months to confirm that current medical necessity criteria are met, that the medication is effective, and there is no concurrent opioid use.

When Policy Topic is not covered

Buprenorphine products are considered investigational when used for all other conditions, including but not limited to: treatment of pain, treatment of other substance dependence, concurrent treatment of pain and opioid dependence.

Considerations

Some contracts do not cover opioid dependence (chemical dependency). When a buprenorphine product is used for opioid dependence; it is not coverable under these contracts. If a buprenorphine product for opioid dependence is a covered benefit, policy criteria will be applied to determine coverage.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Hayes Medical Technology Directory, Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Buprenorphine/naloxone and buprenorphine are orally administered medications used to treat patients with opioid dependence.

Rationale

Buprenorphine and buprenorphine/naloxone are used for office-based management treatment of opioid dependence, whereas methadone needs to be administered in a methadone clinic.

Naloxone has poor sublingual absorption but good parenteral bioavailability. Injection of crushed buprenorphine/naloxone tablets will precipitate opioid withdrawal and may have a lower risk of diversion and parenteral abuse than plain buprenorphine.[1]

There are no studies of buprenorphine/naloxone for treatment of pain. There are no clinical studies showing that buprenorphine/naloxone remains effective in the treatment of opioid dependence when it is combined with other opioids.

Clinical Efficacy

OPIOID DEPENDENCE

National treatment guidelines recognize buprenorphine/naloxone and buprenorphine as first-line treatment options for opioid dependence.[2,3] There are no clinical trials demonstrating superior efficacy or safety of buprenorphine/naloxone compared to buprenorphine for treatment of opioid dependence.[2,4,5]

PAIN

There is no useful evidence supporting the efficacy of buprenorphine/naloxone in the treatment of pain, as there are no studies of buprenorphine/naloxone for treatment of pain. Buprenorphine/naloxone offers no proven additional clinical value over many generic alternatives for treatment of pain.

Treatment guidelines do not recognize buprenorphine/naloxone as an option of management of pain.[6,7] The NCCN specifically recommends against the use of partial agonists, such as buprenorphine, as well as mixed agonist-antagonists in opioid-dependent patients, due to limited utility for treatment of pain and risk of potentiation of withdrawal.[8]

OTHER SUBSTANCE DEPENDENCE

There is no useful evidence supporting the efficacy of buprenorphine/naloxone in the treatment of other substance dependence (e.g. cocaine, alcohol, nicotine), as there are no studies of buprenorphine/naloxone for treatment of other substance dependence.

Safety

All options for treatment of opioid dependence have similar side effect profiles. The most common side effects include pain, headache, withdrawal syndrome, nausea, insomnia, sweating, and constipation. [9]

Appendix

Verification of DATA 2000 waiver to prescribe buprenorphine/naloxone for the treatment of opioid addiction[10]

Prescribers must include their DATA 2000 waiver ID number (or "X" number) on prescriptions for opioid addiction treatment medications, in addition to the DEA registration number. The SAMHSA Buprenorphine Physician Locator Web site lists the physicians in each State who have DATA 2000 waivers. (http://www.buprenorphine.samhsa.gov/bwns_locator/index.html) * A physician listed on the site can be considered to have a valid DATA 2000 waiver.

* The list on the site is not complete, as physicians with a valid waiver may choose not to be listed on the site. A pharmacist may verify that a physician has a valid DATA 2000 waiver by calling SAMHSA at 1-866-287-2728 or by e-mail at info@buprenorphine.samhsa.gov.

References:

- 1 Substance Abuse and Mental Health Services Administration (SAMHSA). Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment; 2004. Treatment Improvement Protocol (TIP) Series #40, DHHS Publication No. (SMA) 04 - 3939. [cited November 1, 2010]; Available from: http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf
- 2 American Psychiatric Association. Practice guideline for the treatment of patients with substance use disorders, 2nd ed. 2006. [cited April 1, 2010]; Available from: http://www.psychiatryonline.com/pracGuide/loadGuidelinePdf.aspx?file=SUD2ePG_04-28-06
- 3 National Institute for Health and Clinical Evidence (NICE). NICE technology appraisal guidance 114: Methadone and buprenorphine for the management of opioid dependence. Issue date: January 2007. . [cited April 6, 2010]; Available from: <http://www.nice.org.uk/nicemedia/live/11606/33833/33833.pdf>
- 4 Mattick RP, Kimber J, Breen C, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. *Cochrane Database Syst Rev*. 2008(2):CD002207. PMID: 18425880
- 5 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*. 2003 Sep 4;349(10):949-58. PMID: 12954743
- 6 American Pain Society. National Clinical Guideline. Use of chronic opioid therapy in chronic noncancer pain: evidence review. Published February 10, 2009. [cited April 20, 2010]; Available from: http://www.ampainsoc.org/pub/cp_guidelines.htm
- 7 A National Clinical Guideline. Control of pain in patients with cancer. Edinburgh, Scotland: Scottish Intercollegiate Guidelines Network (SIGN) 2008. [cited April 20, 2010]; Available from: <http://www.sign.ac.uk/pdf/sign106.pdf>
- 8 National Comprehensive Cancer Network (NCCN); Clinical Practice Guidelines in Oncology: Adult Cancer Pain- v.1.2009. [cited October 27, 2010]; Available from: http://www.nccn.org/professionals/physician_gls/PDF/pain.pdf
- 9 Suboxone and Subutex [package insert]. Richmond, VA: Reckitt Benckiser Pharmaceuticals; 2002
- 10 Substance Abuse and Mental Health Services Administration (SAMHSA). Buprenorphine Physician and Treatment Locator. [cited August 18, 2010]; Available from: http://www.buprenorphine.samhsa.gov/bwns_locator/index.html
- 11 Drug Facts and Comparisons 4.0 (electronic version). Wolters Kluwer Health, Inc.

Billing Coding/Physician Documentation Information

N/A Buprenorphine products are a pharmacy benefit.

Additional Policy Key Words

Suboxone
Subutex

Related Topics

N/A

Policy Implementation/Update Information

01/2012 Origination date
01/2013 No changes made to policy
01/2014 No changes made to policy

This Medical Policy is designed for informational purposes only and is not an authorization, an explanation of benefits, or a contract. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there is any exclusion or other benefit limitations applicable to this service or supply. Medical technology is constantly changing and Blue Cross and Blue Shield of Kansas City reserves the right to review and revise medical policy. This information is proprietary and confidential and cannot be shared without the written permission of Blue Cross and Blue Shield of Kansas City.