



MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
08/05/2011	07/01/2016	10/06/2015
Policy Name	Policy Number	
Medication Assisted Therapy (MAT) for Suboxone	Rx-0001	

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Medication Assisted Therapies for Suboxone

- Buprenorphine – Naloxone (Suboxone) Sublingual tablets
- Buprenorphine and naloxone (Suboxone) Sublingual Films
- Buprenorphine (Subutex)
- Buprenorphine and Naloxone Sublingual Tablets (Zubsolv)

B. BACKGROUND

Buprenorphine–Naloxone (Suboxone)/Buprenorphine (Subutex) Zubsolv.

Clinical studies have demonstrated success in withdrawing patients completely from short and long acting opioids or alcohol. It has also been demonstrated that Buprenorphine – Naloxone (Suboxone) is commonly abused by combined usage with opioids and other commonly abused drugs and by diversion to unintended users and for unintended purposes.

Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. Naloxone is a potent antagonist at mu-opioid receptors and produces opioid withdrawal signs and symptoms in individuals physically dependent on full opioid agonists when administered parentally.

CareSource will manage the use of Buprenorphine – Naloxone (Suboxone) / Buprenorphine (Subutex), and Zubsolv by its members through a prior authorization program that assures appropriate indication for and utilization of the drug. Buprenorphine – Naloxone (Suboxone) / Buprenorphine (Subutex) and Zubsolv treatment should be accompanied by an ongoing counseling and psychosocial programs and periodic urine screening to assure compliance with management protocols.



The recommended clinical guidelines for the use of buprenorphine in the treatment of opioid addiction suggest that physicians periodically and regularly screen all patients for substance use and substance-related problems

Complete assessment may require several office visits, but initial treatment should not be delayed during this period. Further recommendations include initial and ongoing drug screening to detect or confirm the recent use of drugs (e.g., alcohol, benzodiazepines, barbiturates), which could complicate patient management. Urine screening is the most commonly used and generally most cost-effective testing method.

Due to the limited access to physicians prescribing Buprenorphine – Naloxone (Suboxone) / Buprenorphine (Subutex) and Zubsolv authorization for treatment will be given ONLY for members who have demonstrated need, are motivated to comply with an addiction management program that includes companion counseling and who remain compliant with proper dosing and abstinence from other opioids. Authorization for maintenance treatment will be discontinued for members non-compliant with a defined treatment program or utilizing other opioids.

C. DEFINITIONS

N/A

D. POLICY

- I. CareSource will approve the use of Buprenorphine – Naloxone (Suboxone) / Buprenorphine (Subutex), Zubsolv and Narcan, and consider their use as medically necessary when the following criteria have been met for:
 - **Opioid Use Disorder (formerly called “Opioid Dependence”)**
 - **Opioid Intoxication (Narcan only)**

NOTE: Requests for other uses should be reviewed using the CareSource Policy for Off-Label Use and Excluded Indications.

A. Opioid Dependence/opioid use disorder

1. Prior Authorization Criteria: **Suboxone, Subutex, and Zubsolv** are considered medically necessary when criteria are met for **ALL** of the following:
 - 1.1 **Initial requests:**
 - a. The physician is a DATA 2000 waived physician
 - b. A documented diagnosis of opioid use disorder and/or other dependency exists
 - c. Prescriptions are written by a physician with an appropriate DEA number associated with an “X” prefix
 - d. Individual is 16 years of age or older
 - e. Individual must participate in a comprehensive rehabilitation program that includes psychosocial treatment (documentation of treatment plan and taper strategy not required, but verification upon request must be provided)
 - f. Patients do not have opioid claims within the last 30 days while concurrently taking Buprenorphine – Naloxone (Suboxone) / Buprenorphine (Subutex), Zubsolv, (Note: opioid claims may have occurred within 30 days prior to induction and would not be excluded from prior authorization)
 - g. Patient has not had more than 2 failures of Buprenorphine – Naloxone (Suboxone) / Buprenorphine (Subutex), Zubsolv, Vivitrol, Methadone treatment requiring restarting within a year



1.2 Maintenance Requests:

- a. Individual is being treated for opioid dependence/opioid use disorder
- b. Individual is 16 years of age or older
- c. Prescriber's personal DEA and unique DATA 2000 waiver identification number (that is, X DEA number) provided
- d. Individual must participate in a comprehensive rehabilitation program that includes psychosocial treatment documentation of the treatment plan and taper strategy not required, but verification upon request must be provided)
- e. Provider monitors urine toxicology testing per state requirements
- f. Individual does not have more than one sequential positive urine drug screen for an opioid during ongoing urine drug screening for opioids (documentation of negative result not required, but verification upon request must be provided)
- g. Individual has a positive urine drug screen for buprenorphine to continue treatment, or provider has documented query to a prescription drug monitoring program , or documented proof of random pill counts (documentation of result not required, but verification upon request must be provided)

Note: Documented diagnosis of addiction must be confirmed by the treating physician.

For Medicare Plan members, reference the Applicable National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). Compliance with NCDs and LCDs is required where applicable.

CONDITIONS OF COVERAGE

Methadone is not a covered benefit when used to treat addiction.

Buprenorphine – Naloxone (Suboxone) / Buprenorphine (Subutex) & Zubsolv, will not be covered for the primary treatment of pain

HCPCS

- J0571 – Buprenorphine, oral, 1 mg
- J0572 – Buprenorphine/naloxone, oral, less than or equal to 3 mg (Code Price is per 1 tab/film)
- J0573 – Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg (Code Price is per 1 tab/film)
- J0574 - Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg (Code Price is per 1 tab/film)
- J0575 - Buprenorphine/naloxone, oral, greater than 10 mg (Code Price is per 1 tab/film)

CPT

DATA 2000 - The Drug Addiction Treatment Act of 2000 link:

http://www.buprenorphine.samhsa.gov/waiver_qualifications.html

STATE RULE:

Ohio 4731-11-12	Kentucky 201 KAR 9:270
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AUTHORIZATION PERIOD

Authorizations will be granted for:

Medications	Strengths	Quantity Limit
Buprenorphine with naloxone Sublingual Tablet	All Strengths	24 mg per day –initial approval - 3 months 16 mg per day – continuation of therapy
Suboxone (buprenorphine with naloxone) Sublingual Film	All Strengths	24 mg per day – initial approval – 3 months 16 mg per day – continuation of therapy

Continued treatment may be considered after review of the medical records and progress notes. If there are opioids within the recent authorization period but longer than 30 days ago, a 60 day authorization will be granted and a fax will be sent to the physician informing them of the opioid on record.

ALL authorizations are subject to continued eligibility.

E. REVIEW/REVISION HISTORY

Date Issued: 08/01/2011
 Date Reviewed: 07/01/2012, 07/16/2013, 07/09/2014, 07/25/2014, 01/13/2015
 Date Revised: 05/19/15 – Revisions to add State Rules, Authorizations Table, and criteria change
 10/06/2015 – Revisions regarding illicit drug use.

F. REFERENCES

1. Suboxone [package insert]. Richmond, VA.; Reckitt Benckiser Pharmaceuticals Inc.; August 2014.
2. Subutex [package insert]. Richmond, VA.; Reckitt Benckiser Pharmaceuticals Inc.; August 2014.
3. Substance Abuse and Mental Health Services Administration, Office of Applied Studies (2008). US Dept of Health and Human Services. Results from the 2007 National Survey on Drug Use and Health: National Findings. (NSDUH Series H-34, DHHS Publication No. SMA 08-4343). Rockville, MD.
4. Kakko J, Heilig M, Sarman I. Buprenorphine and methadone treatment of opiate dependence during pregnancy: Comparison of fetal growth and neonatal outcomes in two consecutive case series. *Drug Alcohol Depend.* 2008 Jul 1; 96(1-2):69-78.
5. Maremmani I and Gerra G. Buprenorphine-based regimens and methadone for the medical management of opioid dependence: selecting the appropriate drug for treatment. *Am J Addict* 2010;19: 668-568
6. Nicholls L, Bragaw L, and Ruetsch C. Opioid dependence treatment and guidelines. *J Manag Care Pharm.* 2010 Feb;16(1 Suppl B):S14-21.
7. Jones HE, Martin PR, Heil SM, et al. Treatment of opioid dependent pregnant women: clinical and research issues. *J Subst Abuse Treat* 2008; 35(3): 245-259.
8. Orman JS, Keating GM. Buprenorphine/naloxone: a review of its use in the treatment of opioid dependence. *Drugs.* 2009; 69(5):577-607.
9. Vivitrol [package insert]. Waltham, MA; Alkermes, Inc.; 2013.



10. Methadone. (2015, January 26). Retrieved February 23, 2015, from <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682134.html>
11. http://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm
12. <http://buprenorphine.samhsa.gov/faq.html>
13. <http://codes.ohio.gov/oac/3793:2-3-01>
14. 14. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)
15. Ohio Administrative Code 4732-11-12
Kentucky Code 201 KAR 9:270

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review