PHARMACY POLICY STATEMENT

Original Effective Date	Next Annual Review	Last Revision
08/05/2011	07/01/2018	06/08/2017
Policy Name		**Policy Number**
Medication Assisted Therapy (buprenorphine containing agents)		Rx-0012
Policy Type		
Medical	Administrative	**PHARMACY**	Reimbursement

Pharmacy 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, Pharmacy Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Pharmacy 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 Pharmacy Policy Statement. If there is a conflict between the Pharmacy 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

Contents of Policy

A. INTRODUCTION

Clinical studies have demonstrated success with buprenorphine in withdrawing patients completely from short and long acting opioids or alcohol. It has also been demonstrated that buprenorphine–naloxone 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 containing agents by its members through a prior authorization program that assures appropriate indication for and utilization of the drug. Treatment with these agents should be accompanied by 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 containing agents, 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.

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of patients for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of preferred agents. The CareSource Pharmacy Policy Statement is a guideline for determining health care coverage for our patients with benefit plans covering prescription drugs. Pharmacy Policy Statements are written on selected prescription drugs requiring prior authorization or step therapy. The Pharmacy Policy Statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

NOTE: The Introduction section is for your general knowledge and is not to be construed as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals and is intended for providers. A provider can be a person, such as a doctor, nurse,

psychologist, or dentist. A provider can also be a place where medical care is given, like a hospital, clinic or lab. This policy informs providers about when a service may be covered.

B. DEFINITIONS

1. None applicable.

C. POLICY COVERAGE CRITERIA

1. Site of Service

Site of Service Administration	Coverage Criteria
Outpatient, Home	Preferred place of service is in the home for buprenorphine containing agents. These medications can be self-administered and can be billed through the pharmacy benefit.
Office, Outpatient	Preferred place of service is in a provider's office or outpatient clinic for buprenorphine subdermal implant (Probuphine) as this product must be inserted and removed by a trained healthcare provider only. Probuphine is covered under the medical benefit.

2. Coverage Criteria

Please note that all members approved for medication assisted therapy with buprenorphine containing agents will be required to use generic buprenorphine-naloxone sublingual tablets or generic buprenorphine sublingual tablets first line. If a branded product is being requested following a trial of the generic formulation, please note that a MedWatch report will need to be submitted for therapeutic failure or adverse drug reaction to the FDA. A copy of that report and confirmation of submission must be submitted with prior authorization request along with a chart note as part of the documentation required for prior authorization review. Additional information might be required for claims of therapeutic failure or adverse drug reaction. Please see the Medical Necessity for Non-Formulary Medications policy for more information.

The MedWatch form can be found at: https://www.fda.gov/Safety/MedWatch/

CareSource will approve the use of generic buprenorphine-naloxone sublingual tablet, generic buprenorphine sublingual tablet, or buprenorphine subdermal implant (Probuphine) and consider its use medically necessary when the criteria have been met for each drug or condition listed below. Prior authorization request should be submitted with chart notes and documentation supporting medical necessity.

Condition	Generic buprenorphine-naloxone sublingual tablet or generic buprenorphine sublingual tablet Coverage criteria:
Opioid Dependence / Opioid Use Disorder – Induction Therapy	1) A documented diagnosis of opioid use disorder and/or other dependency exists (*Must include chart notes)* 2) The prescribing physician is a DATA 2000 waivered physician with an appropriate DEA number associated with an "X" prefix or SAMHSA certified 3) Member is 16 years of age or older 4) Member 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*) 5) Member has not had more than 2 failures of buprenorphine containing agents, methadone, or Vivitrol treatment requiring restarting within a year

Condition	Generic buprenorphine-naloxone sublingual tablet or generic buprenorphine sublingual tablet Coverage criteria:
Opioid Dependence / Opioid Use Disorder – Maintenance Therapy	1) A documented diagnosis of opioid use disorder and/or other dependency exists (*Must include chart notes)* 2) The prescriber has a DATA 2000 waiver with an appropriate DEA number associated with an "X" prefix or SAMHSA certified 3) Member is 16 years of age or older 4) Data-waived prescriber must provide documentation to support both of the following: a) One urine drug screen during the last 3 months negative for BOTH full opioid agonists and benzodiazepines (provide dates of tests) b) One urine drug screen during the last 3 months positive for buprenorphine or norbuprenorphine (provide dates of tests) 5) Any positive urine drug screen (UDS) for a non-prescribed controlled substance during maintenance therapy requires ONE or more of the following: a) Pill counts for buprenorphine product have been correct for 30 or more days prior to the positive UDS

	b) Provider discussed additional services to support recovery with member (e.g. counseling) c) Provider recommended a higher level of care 6) Member must participate in a comprehensive rehabilitation program that includes psychosocial treatment (D*ocumentation of treatment plan and taper strategy not required, but verification upon request must be provided*)

Condition	**Buprenorphine subdermal implant (Probuphine) Coverage criteria:**
Opioid Dependence / Opioid Use Disorder – Maintenance Therapy	1) A documented diagnosis of opioid use disorder and/or other dependency exists (*Must include chart notes)* 2) The prescribing physician is a DATA 2000 waivered physician with an appropriate DEA number associated with an "X" prefix or SAMHSA certified 3) Member is 18 to 65 years of age 4) Member 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*) 5) Member must have achieved and sustained prolonged clinical stability on 8 mg/day or less of transmucosal buprenorphine equivalent for at least 3 months without any need for supplemental doses or adjustments. The dose should not have been tapered down to a lower dose for the sole purpose of transitioning to the subdermal implant 6) A documented reason as to why oral therapy should not be continued 7) All REMS Program criteria must be met (see www.probuphinerems.com) 8) Individual must not have used buprenorphine subdermal implant (Probuphine) in the past for a total of 12 months (1 implant in each arm for 6 months each)

All other uses of buprenorphine containing agents are considered experimental/investigational; and therefore, will follow CareSource's off-label policy. Buprenorphine containing agents will not be covered for the primary treatment of pain. Methadone is not a covered benefit when used to treat addiction.

Please note that this policy is reviewed on an annual basis. New drugs and indications receiving FDA approval may not be reflected in this policy immediately.

Notes:

- Documented diagnosis must be confirmed by portions of the individual's medical record which need to be supplied with prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider's office, or hospital admission notes.
- Member is required to have completed the trial(s) listed in the above criteria unless the member is unable to tolerate or has a contraindication to trial medications. Documentation such as chart notes or pharmacy claims may be requested to verify trial(s), intolerance, or contraindication(s).
- Refer to the product package insert for dosing, administration and safety guidelines.
- Use of buprenorphine in combination with naloxone is not recommended during pregnancy.
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3. Dosage and Quantity Limits (listed if applicable)

Information for patients with renal or hepatic impairment is not included. See package insert for individual agents.

Drug	Dosage and Quantity Limits
Generic buprenorphine-naloxone sublingual tablets	Literature does not support the use of doses greater than 16 mg of buprenorphine per day. CareSource reserves the right to request additional information and documentation for doses greater than 16 mg.
Generic buprenorphine sublingual tablets	Literature does not support the use of doses greater than 16 mg of buprenorphine per day. CareSource reserves the right to request additional information and documentation for doses greater than 16 mg.
Buprenorphine subdermal implant (Probuphine)	1 subdermal implant for 6 months. Limited to 2 treatments for a total duration of treatment of 12 months.

4. Authorization Period

Condition	Approval Period
Opioid Dependence / Opioid Use Disorder – Induction Therapy	The initial authorization of **generic buprenorphine-naloxone or buprenorphine sublingual tablets** is valid for 3 months for induction therapy.
Opioid Dependence / Opioid Use Disorder – Maintenance Therapy	The authorization of **generic buprenorphine-naloxone or buprenorphine sublingual tablets** is valid for 12 months for maintenance therapy if dose of buprenorphine is 16 mg per day or less. If dose is 16 to 24 mg per day, the authorization is valid for 6 months for maintenance therapy.

	Continued maintenance therapy may be considered after review of the medical records and progress notes. 1) The data-waived prescriber must provide documentation to support TWO or more of the following: a) One urine drug screen during the last 3 months negative for BOTH full opioid agonists and benzodiazepines (provide dates of tests) b) One urine drug screen during the last 3 months positive for buprenorphine or norbuprenorphine (provide dates of tests) 2) Any positive urine drug screen (UDS) for a non-prescribed controlled substance during maintenance therapy requires ONE or more of the following: a) Pill counts for buprenorphine product have been correct for 30 or more days prior to the positive UDS b) Provider discussed additional services to support recovery with member (e.g. counseling) c) Provider recommended a higher level of care 3) After consistent use of a buprenorphine product for a duration that exceeds 12 months, CareSource reserves the right to request additional information and documentation showing the member is benefitting from treatment with buprenorphine and whether an evaluation for dose reduction has been completed or attempted. (Verification must be provided upon request) **ALL** authorizations are subject to continued eligibility.
Opioid Dependence / Opioid Use Disorder – Maintenance Therapy	The initial authorization of **buprenorphine subdermal implant (Probuphine)** is valid for 6 months for maintenance therapy. Continued maintenance therapy 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, the authorization request might be denied and a discussion with or notification to prescriber might be warranted. A reauthorization after successful maintenance therapy period will be placed for an additional 6

	months. Total duration of therapy will not be approved past 12 months. **ALL** authorizations are subject to continued eligibility.

5. Coding

HCPCS	
J0570	Buprenorphine subdermal implant (Probuphine)

D. RELATED POLICIES

AD-0004: Medical Necessity - Off-Label, Approved Orphan and Compassionate Use Drugs
AD-0008: Medical Necessity for Non-Formulary Medications

E. REVIEW/REVISION HISTORY

DATE	ACTION/DESCRIPTION
08/11/2011	Date issued
07/01/2012	Annual review
07/16/2013	Annual review
07/09/2014	Annual review
07/25/2014	Reviewed
01/13/2015	Reviewed
05/19/2015	Revisions to add state rules, authorizations table, and criteria change
10/6/2015	Revisions regarding illicit drug use
08/24/2016	Revisions to criteria, addition of Probuphine, and updated references
11/23/2016	Revisions to criteria, separated policy for each line of business, and updated format of policy
1/20/2017	Added statement under coverage criteria regarding use of generic formulations and requirement of MedWatch report. Removed J codes for oral formulations.
1/30/2017	Removed brand name products (Bunavail, Suboxone film, and Zubsolv) from policy.
06/08/2017	Updated urine drug screen requirements and authorization periods. Note about pregnancy added.

F. REFERENCES

1. Suboxone [package insert]. Richmond, VA; Reckitt Benckiser Pharmaceuticals Inc.; June 2016.
2. Subutex [package insert]. Richmond, VA: Reckitt Benckiser Pharmaceuticals Inc.; June 2016.
3. Probuphine [package insert]. Princeton, NJ: Braeburn Pharmaceuticals, Inc.; May 2016.
4. Bunavail [package insert]. Raleigh, NC: Biodelivery Sciences International, Inc.; 2002.
5. Zubsolv [package insert]. Morristown, NJ. Orexo US, Inc.; August 2015.

6. 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.
7. 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.
8. 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.
9. Nicholls L, Bragaw L, and Ruetsch C. Opioid dependence treatment and guidelines. J Manag Care Pharm. 2010 Feb;16(1 Suppl B):S14-21.
10. 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.
11. Orman JS, Keating GM. Buprenorphine/naloxone: a review of its use in the treatment of opioid dependence. *Drugs*. 2009; 69(5):577-607.
12. Vivitrol [package insert]. Waltham, MA; Alkermes, Inc.; 2013.
13. Methadone. (2015, January 26). Retrieved February 23, 2015, from http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682134.html.
14. Drug Enforcement Administration Office of Diversion Control. DEA requirements for DATA waived physicians (DWPs). http://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm
15. Substance Abuse and Mental Health Services Administration. Buprenorphine Waiver Management. Updated 8/17/16. http://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management.
16. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5).
17. Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. J Addict Med. 2015; 9: 1-10.
18. Kentucky Code 201 KAR 9:270.

The Pharmacy Policy detailed above has received due consideration and is approved.

Independent medical review