PHARMACY POLICY STATEMENT **North Carolina Marketplace**	
DRUG NAME	Probuphine (buprenorphine subdermal implant)
BILLING CODE	J0570
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 1 implant in each arm for 6 months each
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Probuphine (buprenorphine subdermal implant) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

OPIOID DEPENDENCE

For **initial** authorization:

1. Member is 18 to 65 years of age; AND
2. Member has a documented diagnosis of opioid use disorder and/or other dependency in char notes; AND
3. Medication must be prescribed by a DATA 2000 waivered physician with an appropriate DEA number associated with an "X" prefix or SAMHSA certified; AND
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); AND
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; AND
6. A documented reason as to why oral therapy should not be continued; AND
7. All REMS Program criteria must be met (see www.probuphinerems.com).
8. **Dosage allowed:** 1 implant in one arm for 6 months, 1 implant in the opposite arm for a total of 12 months of therapy. Implants should not be used for additional treatment cycles after one insertion in each upper arm.

Note: Use of buprenorphine subdermal implant (Probuphine) is limited to a total duration of 12 months (1 implant in each arm for 6 months each).

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
Probuphine will not be reauthorized.

CareSource considers Probuphine (buprenorphine subdermal implant) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
04/03/2019	Policy for Probuphine modified into a new format.
03/11/2021	Annual review, no changes

References:

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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. Drug Enforcement Administration Office of Diversion Control. DEA requirements for DATA waived physicians (DWPs). http://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm.
10. Substance Abuse and Mental Health Services Administration. Buprenorphine Waiver Management. Updated 8/17/16. http://www.samhsa.gov/medication-assistedtreatment/buprenorphine-waiver-management.
11. Ohio. 5122-29-35. Licensure to conduct an opioid agonist program.
12. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)
13. Ohio Administrative Code 4731-11.
14. 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.

Effective date: 01/01/2023
Revised date: 03/11/2021