Probuphine (buprenorphine implant)
Policy Number: C10952-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
6/1/2017	12/18/2019	12/18/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J0570-buprenorphine implant, 74.2mg	RxPA	Q1 2020 20200122C10952-A

PRODUCTS AFFECTED:
Probuphine Implant Kit implant 74.2MG

DRUG CLASS:
Opioid Partial Agonists

ROUTE OF ADMINISTRATION:
Subcutaneous

PLACE OF SERVICE:
Specialty Pharmacy or Buy and Bill

AVAILABLE DOSAGE FORMS:
Probuphine Implant Kit implant 74.2MG

FDA-APPROVED USES:
indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine-containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet equivalent or generic equivalent).
F11.20 Opioid dependence, uncomplicated, F11.21 Opioid dependence, in remission

COMPENDIAL APPROVED OFF-LABELED USES:
None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
Opioid use disorder

REQUIRED MEDICAL INFORMATION:
A. OPIOID USE DISORDER:
1. Documentation of member's requirement for maintenance treatment
   AND
2. Documentation of clinical stability (for at least 3 months)on a transmucosal buprenorphine-containing product, without any need for supplemental dosing or dose adjustment. Maintenance dosing cannot exceed the following: Buprenorphine sublingual tablet 8 mg per day, Buprenorphine/naloxone sublingual tablet 8 mg / 2 mg per day, Zubsolv sublingual tablet

5.7 mg / 1.4 mg per day or Bunavail buccal film 4.2 mg / 0.7 mg per day

NOTE: clinically stable as defined by the following: No reports of any illicit opioid use, No reports of significant withdrawal symptoms, Reports of low to no desire/need to use illicit opioids, No episodes of hospitalizations (addiction or mental health issues), emergency room visits, or crisis interventions in the past 90 days, consistent participation in recommended cognitive behavioral therapy/peer support program and consistent compliance with clinic visit requirement
AND

3. Member is a new start on Probuphine or has received ONE previous 6-month course of Probuphine (maximum of 1 insertion).
AND
4. Documentation member has been given a prescription for burprenorphine for as needed use and will remain in a counseling program and be compliant with clinic visits and drug screens
AND
5. Documentation prescriber has counseled patients of the potential danger of self-administration of benzodiazepines or other CNS depressants while under treatment with PROBUPHINE

DURATION OF APPROVAL:
Initial authorization: 6 months. Continuation of therapy: 6 months
After one insertion in each arm, discontinue treatment with subdermal implants.

QUANTITY:
4 implants (1 package) per 168 day supply

PRESCRIBER REQUIREMENTS:
Prescribed by prescriber who has unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine and must be certified by the Probuphine REMSprogram. Must be implanted by a healthcare provider who is certified by the Probuphine MS program

AGE RESTRICTIONS:
16 years of age or older

CONTINUATION OF THERAPY:
A. OPIOID USE DISORDER:
1. Documentation member is benefiting from Probuphine therapy
AND
2. Documentation the member has sustained clinical stability on Probuphine
AND
3. Member has not already received a maximum of two 6-month cycles of Probuphine (maximum of 2 insertions)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Probuphine (buprenorphine implant) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.

OTHER SPECIAL CONSIDERATIONS:
Probuphine should be used as part of a complete treatment program to include counseling and psychosocial support. Probuphine is not appropriate for new entrants to treatment and patients who have not achieved and sustained prolonged clinical stability, while being maintained on buprenorphine 8 mg per day or less of a Subutex or Suboxone sublingual tablet equivalent or generic equivalent.

BACKGROUND:
Probuphine is indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a sublingual or transmucosal buprenorphine containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet or generic equivalent). Each Probuphine implant is an ethylene vinyl acetate (EVA) implant, 26 mm in length and 2.5 mm in diameter, containing 74.2 mg of buprenorphine (equivalent to 80 mg of buprenorphine hydrochloride). Probuphine should be used as part of a complete treatment program to include counseling and psychosocial support. Probuphine is not appropriate for new entrants to treatment and patients who have not achieved and sustained prolonged clinical stability, while being maintained on buprenorphine 8 mg per day or less of a Subutex or Suboxone sublingual tablet or generic equivalent. Probuphine is available only through a restricted REMS program, called the “Probuphine REMS Program”, because of the risk of complications of migration, protrusion and expulsion, and nerve damage associated with the insertion and removal of Probuphine.
Notable requirements of the “Probuphine REMS Program” include the following: Healthcare Providers who Prescribe Probuphine must be certified with the program by enrolling and completing live training, Healthcare Providers who Insert Probuphine: o must meet the prerequisite requirements o be certified with the program by enrolling and completing live training, including demonstrating competency in Probuphine procedures, Patients must be monitored to ensure that Probuphine is removed by a healthcare provider certified to insert/remove Probuphine implants, Probuphine will only be distributed to certified prescribers through a restricted distribution program. There is no experience with inserting additional implants into other sites in the arm to recommend an approach to a second insertion into a previously-used arm. Neither re-insertion into previously-used administration sites, nor into sites other than the upper arm, have been studied. It is important to avoid previously-implanted sites because the effect of scarring and fibrosis in previously-used insertion sites on either the effectiveness of Probuphine or the safety of insertion have not been evaluated. After one insertion in each arm, additional cycles of treatment should only be considered if the potential benefits of continuing Probuphine outweigh the potential risks of additional insertion and removal procedures, taking into account the experience of the health care provider with Probuphine procedures and related procedures, and the clinical need of the patient for ongoing treatment with subdermal medication. In most cases, patients should be transitioned back to a transmucosal buprenorphine-containing product for continued treatment.

APPENDIX:
Substance Abuse and Mental Health Services Administration (SAMHSA) Verification of DATA-Certified Physicians
Effective July 25, 2005, physicians must include their DATA 2000 waiver ID number on prescriptions for opioid addiction treatment medications. The practitioner's DEA registration number and the unique identification number (DATA 2000 waiver ID number or "X" number) must be on the

prescription 21 CFR 1306.05(a). The identification number is not in lieu of the DEA registration number, it is an addition. If the prescription is telephoned to the pharmacy, the pharmacist must have both of these numbers on the prescription record so the physician can provide the numbers or the pharmacist may have them on file.
The SAMHSA Buprenorphine Physician Locator website lists the physicians in each State who have DATA 2000 waivers. A physician listed on the site can be considered to have a valid DATA 2000 waiver. Note, however, that the site does not list every physician with a valid waiver, only those who have agreed to be listed on the site. Physicians with valid waivers may choose not to be listed on the site.
A person desiring to verify that a physician who is not listed on the site has a valid DATA 2000 waiver can contact SAMHSA by phone at 1-866-BUP-CSAT (1-866-287-2728) or by e-mail at infobuprenorphine@samhsa.hhs.gov. The verifying person should convey their DEA registration number with these requests.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. Probuphine (buprenorphine) [prescribing information]. Princeton, NJ: Braeburn Pharmaceuticals Inc; October 2019.
2. Probuphine (buprenorphine HCl) Implant CIII Treatment of Opioid Dependence: Briefing Document For the FDA Advisory Committee Meeting. Braeburn Pharmaceuticals. fda.gov. Prepared Dec 11, 2015. Available from: http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/psychopharmacologicdrugsadvisorycommittee/ucm480733.pdf.
3. Probuphine (Buprenorphine Hydrochloride Implant) Psychopharmacologic Drugs Advisory Committee [PowerPoint slides]. Braeburn Pharmaceuticals. Presented January 12, 2016. Retrieved 05/31/2016.
4. Center for Substance Abuse Treatment. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol(TIP) Series 40. DHHS Publication No. (SMA)04-3939. Rockville, MD: Substance Abuse and Mental Health Services