



## Prior Authorization Criteria

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### PROBUPHINE® (Buprenorphine Implant) PA Criteria

- Probuphine, a partial opioid agonist, 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 transmucosal buprenorphine-containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet equivalent, Bunavail 4.2 mg/0.7 mg or less, or Zubsolv 5.7 mg/1.4 mg or less) or generic equivalent. Probuphine should only be used in patients who are opioid tolerant.

\*See Probuphine package insert for healthcare providers' attestation determinants for patient clinical stability. (Clinical Studies' section)

- 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.
- The prescriber and the healthcare provider performing insertion must have successfully completed a live training program specific to Probuphine insertion.
- Under the Drug Addiction Treatment Act (DATA) codified at 21 United States Code (U.S.C.) 823(g), use of Probuphine in the treatment of opioid dependence is limited to healthcare providers who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe or dispense this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription. Thus the prescriber must meet DATA 2000 requirements\*\* and has been assigned a unique identification number specific to the prescription of medication assisted therapy (X-DEA).
- All buprenorphine prescribers must have a current X-DEA number.

*\*\*Substance Abuse and Mental Health Services Administration (SAMHSA) Verification of DATA-Certified Physicians*

*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.*

*Buprenorphine Treatment Physician Locator:*

- <http://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator>

To verify a physician's data waiver, by searching his or her last name and DEA registration number, pharmacists can use the following website:

- <https://www.samhsa.gov/bupe/lookup-form>

Additionally, 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](mailto:infobuprenorphine@samhsa.hhs.gov). The verifying person should convey their DEA registration number with these requests.

Probuphine is not available in retail pharmacies and have limited specialty pharmacy distribution.

Probuphine should be used as part of a complete treatment program to include counseling and psychosocial support.

### **Probuphine Implant Authorization Criteria**

#### **Initial Authorization (must meet all) - Authorization is for 6 months**

- Age  $\geq$  16 years, **and**
- Diagnosis of Opioid Dependence, **and**
- Currently on a maintenance dose of  $\leq$  8mg/day of oral buprenorphine or buprenorphine-naloxone oral, sublingual or transmucosal film (members should not be tapered down to a lower dose for the sole purpose of transitioning to Probuphine) for 90 days or longer without any need for supplemental dosing or adjustments, **and**
- Beneficiary will not be receiving supplemental oral, sublingual or transmucosal buprenorphine after implant insertion, **and**
- Beneficiary has not had an opioid-positive urine drug screen within the previous 90 days prior to insertion, **and**
- Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria upon request,\*\*\* **and**
- Dose does not exceed 4 implants/6 months:
  - Four implants are inserted subdermally in the upper arm for 6 months and are removed by the end of the 6<sup>th</sup> month.

#### **Continuation of therapy (must meet all). Authorization is for 6 months for the second set of four implants**

- Patient has experienced a treatment success to Probuphine therapy, **and**
- One of the following is met (**a or b**):
  - Beneficiary has not received an opioid analgesic since last approval
  - Prescriber submits documentation acknowledging that the use of any opioid during the last approval period was due to diagnosis of acute pain **and**

- Patient has not, nor will receive supplemental oral, sublingual, or transmucosal buprenorphine\*\*\*, **and**
- Patient has not had an opioid-positive urine drug screen since starting Probuphine therapy, **and**
- Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria upon request,\*\*\* **and**
- Probuphine is only to be used in a maximum of 2 insertions (once in each arm)
  - Probuphine is not being inserted into a previously used arm or insertion site.
  - Probuphine should not be used for additional treatment cycles after one set of 4 implants inserted **in each** upper arm, **and**
  - After one insertion in each arm, most patients should be transitioned back to a transmucosal buprenorphine-containing product for continued treatment, **and**
- Patient shows no evidence of tampering, extraction, or attempted removal of the previous Probuphine implant.

\*\*\*Patients screening positive for opioid use outside of an opioid dependence treatment regimen is evidence that the patient has not achieved or is no longer in sustained, prolonged, clinical stability with their treatment program. Use of Probuphine is not indicated in this population UNLESS the prescriber submits documentation acknowledging that the use of any opioid during the last approval period was due to diagnosis of acute pain.

**Probuphine is unproven and/or not medically necessary for beneficiaries who:**

- Have not achieved and sustained prolonged clinical stability and tolerance to opioids for at least 6 months.
- Are maintained on oral, sublingual or transmucosal buprenorphine at does greater than 8mg/day.
- Are recently tapered to a lower dose of oral, sublingual or transmucosal buprenorphine for the sole purpose of transitioning to Probuphine.
- Are new entrants to opioid dependence treatment.
- Have already had one insertion in each arm.
- Do not have viable sites for insertion in the upper arm.
- Have an opioid-positive urine drug screen within the previous 90 days.
- Are currently being treated for chronic pain requiring opioids.

**Probuphine REMS Program**

**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:
  - Must meet the prerequisite requirements

- Must 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.

### **Dosing**

Probuphine implants should be used only in patients who are opioid tolerant. Each dose consists of four Probuphine implants inserted subdermally in the inner side of the upper arm. Probuphine subdermal implants are intended to be in place for 6 months of treatment. Remove Probuphine implants by the end of the sixth month. **After one insertion in each arm, most patients should be transitioned back to a transmucosal buprenorphine-containing product for continued treatment.**

### **How Supplied**

Each Probuphine (buprenorphine) implant kit consists of 4 individually packaged sterile implants and one individually packaged sterile disposable applicator. Each implant is 26 mm in length and 2.5 mm in diameter. Each implant contains 74.2 mg buprenorphine (equivalent to 80 mg buprenorphine hydrochloride).

Probuphine is designed to be implanted subdermally by a trained medical professional and to provide sustained delivery of buprenorphine for up to six months.

Four Probuphine rods deliver circulating drug blood levels comparable to the average plasma concentrations observed following daily doses of  $\leq 8$  mg buprenorphine or buprenorphine/naloxone sublingual or transmucosal products.