Probuphine (buprenorphine implant)

Override(s)	Approval Duration
Prior Authorization	Initial treatment: 6 months Continuation of treatment: 6 additional months

Medications
Probuphine (buprenorphine implant)

APPROVAL CRITERIA

Requests for initial treatment* for Probuphine (buprenorphine implant) may be approved if the following criteria are met:

I. The individual has been diagnosed with opioid dependence (opioid use disorder); **AND**
II. The individual is currently on a maintenance dose** of 8 mg per day or less of a buprenorphine sublingual tablet or its transmucosal buprenorphine product equivalent without any need for supplemental dosing or adjustments for 3 months or longer to achieve sustained prolonged clinical stability on transmucosal buprenorphine; **AND**
III. Probuphine is used as part of a substance use disorder treatment program to include counseling and psychosocial support.

* Initial treatment with buprenorphine implant consists of one 6-month period, involving subdermal placement of the implants in the inner side of the upper arm on one side of the body. Implants must be removed at the end of the sixth month following insertion. If indicated, a second set of implants may be placed in the contralateral arm. The second set of implants should be removed at the end of the second 6 month treatment period.

**The FDA indications specify that maintenance dose should not be tapered to a lower dose for the sole purpose of transitioning to Probuphine.

Requests for Probuphine (buprenorphine implant) may **not** be approved for to the following criteria:

I. All other indications not included above; **OR**
II. For new entrants to treatment; **OR**
III. For individuals who have not achieved and sustained prolonged clinical stability while being maintained on 8 mg per day or less of a sublingual tablet or its transmucosal buprenorphine product equivalent; **OR**
IV. For individuals not enrolled in a substance use disorder treatment program to include counseling and psychosocial support; **OR**
V. For retreatment after a prior 12 month treatment period.

Key References:

1. Clinical Pharmacology powered by ClinicalKey. Tampa (FL): Elsevier. 2020. Available from: http://www.clinicalkey.com.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 13, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.