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 has been treated with a stable transmucosal buprenorphine dose (of 8 mg per day or less of a sublingual tablet or its transmucosal buprenorphine product equivalent) for 3 months or longer without any need for supplemental dosing or adjustments; **AND**
III. The individual is currently on a maintenance dose** of 8 mg per day or less of a sublingual tablet or its transmucosal buprenorphine product equivalent to achieve sustained prolonged clinical stability on transmucosal buprenorphine; **AND**
IV. 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. For new entrants to treatment; **OR**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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II. 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**

III. For individuals not enrolled in a substance use disorder treatment program to include counseling and psychosocial support; **OR**

IV. For retreatment after a prior 12 month treatment period.

### State Specific Mandates

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**Key References:**

4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.