Probuphine (buprenorphine implant)  
DRUG.00092

Override(s) | Approval Duration
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Prior Authorization | Initial treatment: 6 months  
Continuation of treatment: 6 additional months  
Treatment beyond 12 months (1 year) is considered investigational and not medically necessary.

Medications | Quantity Limit
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Probuphine® (buprenorphine implant) | N/A

**APPROVAL CRITERIA**

I. Initial treatment with Probuphine* (buprenorphine implant) is considered **medically necessary** when ALL of the following criteria have been met:

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

* Initial treatment with Probuphine 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 6th 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.
Investigational and Not Medically Necessary:

Treatment with Probuphine is considered **investigational and not medically necessary** for all other indications, including but not limited to:

1. When the medically necessary criteria above have not been met.
2. For new entrants to treatment.
3. For individuals 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.
4. For individuals not enrolled in a comprehensive substance use disorder treatment program.

Treatment for longer than 12-months with Probuphine is considered **investigational and not medically necessary** under all circumstances†.

†Individuals can be transitioned back to transmucosal buprenorphine-containing medications for continued treatment after 12 months as needed.

Retreatment with Probuphine after a prior 12-month treatment period is considered **investigational and not medically necessary** under all circumstances.

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**State Specific Mandates**

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<th>State name</th>
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**Key References:**


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.

WEB-PEC-0506-16
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WEB-PEC-0506-16

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*FHK- Florida Healthy Kids


DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.