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.

Probuphine (buprenorphine implant)

**Override(s) & Approval Duration**

<table>
<thead>
<tr>
<th>Override(s)</th>
<th>Approval Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Initial treatment: 6 months</td>
</tr>
<tr>
<td></td>
<td>Continuation of treatment: 6 additional months</td>
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<tr>
<td></td>
<td>Treatment beyond 12 months (1 year) is considered investigational and not medically necessary.</td>
</tr>
</tbody>
</table>

**Medications**

Probuphine\textsuperscript{®} (buprenorphine implant)

**APPROVAL CRITERIA**

I. Initial treatment with Probuphine\* (buprenorphine implant) may be approved 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 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 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 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.

Probuphine is may **not** be approved for all other indications, including but not limited to:
   A. When the medically necessary criteria above have not been met.
B. For new entrants to treatment.
C. 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.
D. For individuals not enrolled in a comprehensive substance use disorder treatment program.

Treatment for longer than 12-months with Probuphine may not be approved 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 may not be approved under all circumstances.

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### State Specific Mandates

<table>
<thead>
<tr>
<th>State name</th>
<th>Date effective</th>
<th>Mandate details (including specific bill if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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### Key References:

*FHK- Florida Healthy Kids

| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
|--------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|----|
| Applicable | X | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | X |

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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