Medical Drug Clinical Criteria

Subject:	Implantable and ER Buprenorphine Containing Agents		
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Overview

This document addresses the use of implantable products containing buprenorphine, including Probuphine® and buprenorphine extended-release injection.

Probuphine, the first buprenorphine implant, is intended for maintenance treatment of opioid use disorder in individuals who have achieved and sustained prolonged clinical stability on low-to-moderate doses of buprenorphine (for example, doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet or generic equivalent). Probuphine is designed to be implanted subcutaneously into the inside of the upper arm and is formulated to provide 6 months of consistent low-dose buprenorphine therapy without the need for daily oral administration, which is intended to eliminate adherence issues.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Probuphine (buprenorphine implant)

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 buprenorphine implant.

Requests for Probuphine (buprenorphine implant) may not be approved for 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.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT

11981	Insertion, non-biodegradable drug delivery implant [when specified as insertion of Probuphine implant]
11983	Removal with reinsertion, non-biodegradable drug delivery implant [when specified as insertion of Probuphine implant]

HCPCS

G0516	Insertion of non-biodegradable drug delivery implants, 4 or more (services for subdermal rod implant)
G0517	Removal of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)
G0518	Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)
J0570	Buprenorphine implant, 74.2 mg [Probuphine]

ICD-10 Diagnosis

F11.10-F11.99	Opioid related disorders

Document History

Reviewed: 08/19/2022
Document History:

- 08/19/2022 – Annual Review: No changes. Coding reviewed: No changes.
- 08/20/2021 – Annual Review: No changes. Coding reviewed: No changes.
- 08/21/2020 – Annual Review: Updated may not be approved criteria. Coding Review: No changes.
- 08/16/2019 – Annual Review: Wording and formatting changes to Probuphine; Retire Sublocade criteria. Coding Reviewed: Removed J3490, Q9991, Q9992 for Sublocade deletion.
- 08/17/2018 – Annual Review: Initial review of CG-DRUG-89; Annual review. Updated requirement for SUD treatment program – removed “comprehensive” and verified program was to include counseling and psychosocial support.
- 11/9/2018 – Coding review: no changes needed.

References

1. Clinical Pharmacology powered by ClinicalKey. Tampa (FL): Elsevier. 2022. 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 6, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; 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.