Medical Coverage Policy | Buprenorphine for Treatment of Opioid Dependence

EFFECTIVE DATE: 01|01|2017
POLICY LAST REVIEWED: 02|05|2025

OVERVIEW

Buprenorphine is a partial μ-opioid agonist used to treat patients with an opioid addiction. Administered transmucosally, buprenorphine can be used with or without naloxone, which is an opioid antagonist. Though effective, a clinical strategy of using transmucosal buprenorphine is prone to nonadherence, diversion, abuse, and accidental misuse. To lower these risks and improve adherence. A buprenorphine (Probuphine) implant has been developed to provide sustained delivery of buprenorphine for up to 6 months via 4 subdermally inserted rods. Probuphine is intended as a maintenance treatment for a select subgroup of opioid-dependent patients who are clinically stable on a low dose of transmucosal buprenorphine (≤8mg/d). These implants are inappropriate for new treatment recipients and those who do not have sustained and prolonged clinical stability while being maintained on a generic equivalent of buprenorphine.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Buprenorphine subdermal implants is considered medically necessary for individuals who have been:

- diagnosed with opioid dependence; and
- treated with a stable transmucosal buprenorphine dose (≤8 mg/d of a sublingual Subutex or Suboxone tablet or its transmucosal buprenorphine product equivalent) for 3 months or more without any need for supplemental dosing or adjustments; and
- currently on a maintenance dose[a] of 8 mg per day or less of a sublingual Subutex or Suboxone tablet or its transmucosal buprenorphine product equivalent to achieve sustained prolonged clinical stability on transmucosal buprenorphine; and
- Buprenorphine implants are used as part of a comprehensive substance use disorder treatment program that includes counseling and psychosocial support.

U.S. Food and Drug Administration indications specify that maintenance doses should not be tapered to a lower dose for the sole purpose of transitioning to buprenorphine implants.

Use of buprenorphine implants greater than 2 times per lifetime is not medically necessary as the FDA labeling prohibits use after two 6-month doses.

Under the Drug Addiction Treatment Act (DATA) codified at 21 United States Code (U.S.C.) 823(g), use of this product in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe or dispense this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage for applicable physician administered drug benefits/coverage.

BACKGROUND

Opioid Misuse

Opioids were involved in 49,860 overdose deaths in 2019 (70.6% of all drug overdose deaths).

Treatment

Buprenorphine is among the main options in a medication-assisted treatment strategy for opioid dependence. Transmucosal buprenorphine products have a potential for diversion to an illicit drug market and have resulted in accidental poisonings of small children.

To minimize the misuse, Braeburn Pharmaceuticals developed Probuphine, an implantable buprenorphine that would be difficult to divert or abuse, and therefore would less likely be accidentally ingested by children. Further, as an implant, it would maximize adherence passively for 6 or 12 months.

The initial new drug application, submitted by Braeburn in October 2012, sought approval of buprenorphine implants for initial treatment of patients with opioid dependence after just a few days of titration on a transmucosal formulation. The U.S. Food and Drug Administration issued a complete response letter for this new drug application, stating that, although the two 6-month trials met the prespecified end points, the dose provided by the implant "was too low to provide effective treatment for patients new to buprenorphine treatment." However, data from a subset of patients revealed that 4 buprenorphine implants yielded buprenorphine concentrations similar to those observed with sublingual buprenorphine(anywhere from 4 to 8 mg based on average exposure [eg, mean area under the receiver operating characteristic curve values] or concentration). Thus, a subset of patients stabilized on sublingual buprenorphine 8 mg or less could benefit from buprenorphine implants, which is the current target population for which these implants are approved.

Regulatory Status

On May 26, 2016, buprenorphine implant (Probuphine®; Braeburn Pharmaceuticals; NDA 204442) was approved by the U.S. Food and Drug Administration through the new drug application process for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of an agent containing transmucosal buprenorphine (ie, doses of ≤8 mg/d of SubutexÒ or Suboxone® [Indivior] sublingual tablet or generic equivalent). In May 2018, Titan Pharmaceuticals, Inc. was granted exclusive rights to commercialize and develop Probuphine®. On October 19, 2020, Titan Pharmaceuticals announced in October 2020 plans to discontinued sales of buprenorphine implant for financial reasons.

This evidence review was created in October 2016 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through May16, 2022.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events

and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

CODING

Medicare Advantage Plans and Commercial Products

The follow code(s) are covered:

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 (Code Deleted Effective 12/31/2024)

RELATED POLICIES

Not Applicable

PUBLISHED

Provider Update, April 2025
Provider Update, March 2024
Provider Update, December 2023
Provider Update, October 2022
Provider Update, May 2021

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