

Corporate Medical Policy

Buprenorphine Implant for Treatment of Opioid Dependence

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Description of Procedure or Service

Over the past decade, opioid dependence has become an epidemic in the U.S. Americans represent less than 5% of the world's population, but are by far the largest group of opioid users. In fact, 80% of the world's supply of opioids and 99% of the hydrocodone supply is used by people in the United States. The CDC estimates approximately 2.2 million people in the U.S. are abusing opioids and 1.8 million people are dependent, meaning they are unable to stop taking opioids without experiencing withdrawal.

While the abuse of opiates in the U.S. has risen drastically, innovation in long-term treatments for dependence has not. Only three medication assisted therapies (MAT) have gained U.S. approval to treat opioid dependence in the last 30 years. The most common and successful MAT options use opioid replacement therapy, including methadone or sublingual buprenorphine. The approval of buprenorphine and the Drug Addiction Treatment Act of 2000 enabled physicians to treat opioid dependence in an office-based setting, dramatically improving patient access to treatment. These treatment approaches have helped many opiate users but are accompanied by challenging aspects that patients and physicians must consider, including intentional and unintentional non-compliance, potential for diversion and accidental pediatric exposure.

Buprenorphine is a partial μ -opioid agonist used with or without naloxone, an opioid antagonist, via transmucosal delivery to treat patients with opioid dependence (or moderate-to-severe opioid use disorder). Though effective, a clinical strategy of using transmucosal buprenorphine is prone to nonadherence, diversion, abuse, and accidental misuse. To lower these risks and to improve adherence, Braeburn Pharmaceuticals devised buprenorphine (Probuphine[®]), an implant to provide sustained delivery of buprenorphine for up to 6 months when 4 rods are inserted subdermally. It is intended as a maintenance treatment for a selected subgroup of opioid-dependent patients who are clinically stable on a low-to-moderate doses of transmucosal buprenorphine (≤ 8 mg/d). These implants are inappropriate for new treatment recipients or those who have not sustained and prolonged clinical stability, while being maintained on a generic equivalent of buprenorphine.

Each implant is a sterile, single, soft, flexible, rod-shaped ethylene vinyl acetate (EVA) implant, 26 mm in length and 2.5 mm in diameter, containing 74.2 mg of buprenorphine (equivalent to 80 mg of buprenorphine hydrochloride). Each dose consists of four implants inserted subdermally in the inner side of the upper arm. The implants are intended to be in place for six months of treatment and removed by the end of the sixth month. New implants may be inserted subdermally in an area of the inner side of either upper arm that has not been previously used at the time of removal, if continued treatment is desired.

Buprenorphine Implant for Treatment of Opioid Dependence

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for buprenorphine implant for treatment of opioid dependence when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Buprenorphine implants are covered

Buprenorphine subdermal implants may be considered medically necessary when all the following criteria have been met:

1. The individual has been diagnosed with opioid dependence; and
2. The individual has been 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 (*See Policy Guidelines); and
3. The individual is currently on a maintenance dose** 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
4. Buprenorphine implants are used as part of a comprehensive substance use disorder treatment program that includes counseling and psychosocial support.

Inserting up to 4 buprenorphine implants once in each arm at an interval of 6 months may be considered medically necessary.

** 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.

When Buprenorphine implants are not covered

Buprenorphine implants are considered investigational 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;
5. Treatment for longer than 12 months.

Individuals can be transitioned back to transmucosal buprenorphine-containing medications for continued treatment after 12 months as needed. Retreatment with buprenorphine implant after a prior 12-month treatment period is considered investigational and not medically necessary under all circumstances.

Buprenorphine Implant for Treatment of Opioid Dependence

Policy Guidelines

On May 26, 2016, buprenorphine implant (Probuphine®; Braeburn Pharmaceuticals) was approved by the U.S. Food and Drug Administration (FDA) 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 Subutex® or Suboxone® sublingual tablet or generic equivalent). In May 2018, Titan Pharmaceuticals, Inc. was granted exclusive rights to commercialize and develop Probuphine.

Insertion and removal of Probuphine are associated with the risk of implant migration, protrusion, expulsion, and nerve damage resulting from the procedure. Serious but rare complications including nerve damage and migration resulting in embolism and death may result from improper insertion of drug implants inserted in the upper arm. Additional complications may include local migration, protrusion and expulsion. Incomplete insertions or infections may lead to protrusion or expulsion. All Healthcare Providers must successfully complete a live training program and become certified prior to performing insertion and/or removal of Probuphine implants.

Because of the risks associated with insertion and removal, Probuphine is available only through a restricted program called the Probuphine REMS Program. All Healthcare Providers must successfully complete a live training program on the insertion and removal procedures and become certified, prior to performing insertions or prescribing Probuphine implants. Patients must be monitored to ensure that Probuphine is removed by a healthcare provider certified to perform insertions.

The prescribing information includes the following factors in determining clinical stability and suitability for Probuphine treatment:

- Period free from illicit opioid drug use;
- Stability of living environment;
- Participation in a structured activity/job;
- Consistent participation in recommended behavioral therapy/peer support program;
- Consistent compliance with clinic visit requirements;
- Minimal to no desire or need to use illicit opioids;
- Period without episodes of hospitalizations (addiction or mental health issues), emergency room visits, or crisis interventions;
- Social support system.

The prescribing information also provides guidance on acceptable doses of transmucosal buprenorphine that demonstrate stable maintenance dosing:

- Subutex (buprenorphine) sublingual tablet (generic equivalent) 8 mg or less per day;
- Suboxone (buprenorphine and naloxone) sublingual tablet (generic equivalent) 8 mg/2 mg or less per day;
- Bunavail™ (buprenorphine and naloxone) buccal film 4.2 mg/0.7 mg or less per day;
- Zubsolv® (buprenorphine and naloxone) sublingual tablets 5.7 mg/1.4 mg or less per day.

* Initial Coverage (for patients starting therapy with buprenorphine product):

Suboxone (buprenorphine/naloxone sublingual film) or buprenorphine/naloxone sublingual tablet may be eligible for coverage when the following criteria are met:

- The individual is 16 years of age or older; and
- The prescriber meets the qualification certification criteria in the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification

Buprenorphine Implant for Treatment of Opioid Dependence

number, indicating that he/she is a qualified physician under the DATA to prescribe buprenorphine/naloxone (Suboxone); and

- The individual has a diagnosis of opioid dependence; and
- The individual is abstinent from illicit drug use (including problematic alcohol and/or benzodiazepine use); and
- The individual has a psychosocial treatment plan and is compliant with all elements of the treatment plan including:
 - Recovery-oriented activities,
 - Psychotherapy, and/or
 - Other psychosocial modalities.

Bunavail (buprenorphine/naloxone buccal film) may be eligible for coverage when the following criteria are met:

- The individual is 16 years of age or older; and
- The prescriber meets the qualification certification criteria in the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number, indicating that he/she is a qualified physician under the DATA to prescribe buprenorphine/naloxone (Suboxone); and
- The individual has a diagnosis of opioid dependence; and
- The individual is abstinent from illicit drug use (including problematic alcohol and/or benzodiazepine use); and
- The individual has a psychosocial treatment plan and is compliant with all elements of the treatment plan including:
 - Recovery-oriented activities,
 - Psychotherapy, and/or
 - Other psychosocial modalities and
- The individual has experienced a therapeutic failure or inadequate response to generic buprenorphine/naloxone sublingual tablets; or
- The individual has a documented intolerance, FDA labeled contraindication, or hypersensitivity to generic buprenorphine/naloxone sublingual tablets.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: G0516, G0517, G0518, J0570

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 5.01.26, 10/13/16

Prescribing Information available at: <https://braeburnpharmaceuticals.com/>

FDA Briefing Information for the January 12, 2016 Meeting of the Psychopharmacologic Drugs Advisory Committee U.S. Food and Drug Administration. [FDA Advisory Committee](#)

Buprenorphine Implant for Treatment of Opioid Dependence

BCBSA Medical Policy Reference Manual [Electronic Version]. 5.01.26, 8/10/17

Braeburn Pharmaceuticals, Inc. Probuphine (buprenorphine) implant for subdermal administration. Prescribing Information. Princeton, NJ: Braeburn; Revised 2/2018. Available at: https://probuphine.com/wp-content/uploads/2018/02/NDA-204442_Probuphine_Package-Insert-02.2018.pdf. Accessed June 2018.

Specialty Matched Consultant Advisory Panel – 6/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 5.01.26, 8/9/18

Specialty Matched Consultant Advisory Panel – 6/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 5.01.26, 8/8/19

Specialty Matched Consultant Advisory Panel – 6/2020

Policy Implementation/Update Information

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| 12/30/16 | New policy developed. Coverage is provided for buprenorphine implants for the treatment of opioid dependence for those members who meet the medical necessity criteria outlined in the policy. (an) |
| 7/28/17 | Specialty Matched Consultant Advisory Panel review 6/28/2017. No change to policy. (an) |
| 12/15/17 | Codes G0516, G0517, G0518 added to Billing/Coding section. (an) |
| 7/13/18 | Minor grammatical and typographical changes made for clarity. References added. Specialty Matched Consultant Advisory Panel review 6/27/2018. No change to policy statement. (krc) |
| 10/26/18 | Reference added. (krc) |
| 7/30/19 | Specialty Matched Consultant Advisory Panel review 6/19/2019. No change to policy statement. (krc) |
| 8/11/20 | Minor typographical edits made throughout policy for clarity. Reference added. Specialty Matched Consultant Advisory Panel review 6/17/2020. (krc) |

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.