09-J2000-68

Original Effective Date: 09/15/16

Reviewed: 11/08/23

Revised: 04/01/24

Subject: Buprenorphine HCl (Probuphine®) Subdermal Implant and Buprenorphine (Brixadi®, Sublocade®) Subcutaneous Injection

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Opioid dependence has reached a critical level in the United States, in part due to excessive and inappropriate use of opioid drug therapy in pain management and a growing heroin epidemic. Treatment of opioid dependence is complex and should include counseling and psychosocial support in addition to medication-assisted treatment (MAT) with opioid replacement therapy (e.g., methadone, buprenorphine (Subutex®), buprenorphine/naloxone (Bunavail®, Suboxone®, Zubsolv®), and naltrexone (Revia®, Vivitrol®)).

Office-based prescriptions of opioid replacement therapy with buprenorphine alone or Suboxone is restricted by federal and state regulations. Buprenorphine is a partial opioid agonist similar to methadone but with a “ceiling effect” that limits its efficacy at high doses but also is felt to limit its adverse effects. The passing of the federal Drug Addiction Treatment Act (DATA) of 2000 allows qualified physicians to obtain a waiver (also known as an “X” license) to prescribe and/or dispense opioid replacement therapy after receiving special training. Due to abuse and diversion concerns, physicians with a waiver may not treat more than 30 patients concurrently but can apply for a second waiver after one year to treat up to 100 patients at one time.

In May 2016, the U.S. Food and Drug Administration (FDA) approved a new subdermal buprenorphine implant (Probuphine) for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine-containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet equivalent or generic equivalent).

In a randomized clinical trial (n=177) designed to evaluate the noninferiority of buprenorphine implant compared with oral transmucosal buprenorphine (the current standard of care), 90 patients received placebo oral transmucosal buprenorphine and active implants and 87 received placebo implants and active oral transmucosal buprenorphine. Counseling was uniformly provided and additional active oral transmucosal buprenorphine dosages were permitted based on identified signs of relapse.

For the primary outcome, buprenorphine implants were noninferior to oral transmucosal buprenorphine. A total of 81 of 84 patients (96.4%) receiving buprenorphine implants and 78 of 89 patients (87.6%) receiving sublingual buprenorphine were responders, a between-group 8.8% difference. Among the secondary outcomes, buprenorphine implants may have been more effective than sublingual buprenorphine in achieving long-term cumulative opioid abstinence, with response rates at 6 months of 85.7% (72/84 patients) in the implant group and 71.9% (64/89 patients) in the sublingual group (P = .03).

However, as the authors acknowledge, the generalizability of these results is limited, considering the demographic characteristics of the patient population (ie, the majority were white, employed, had at least a high school education, and were dependent on prescription opioids) and that enrollment was limited to stable patients who had maintained opioid abstinence for 90 days prior to randomization and were receiving buprenorphine treatment for several years.

In November 2017, the FDA approved buprenorphine extended-release injection of subcutaneous use (Sublocade) for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product.

The safety and efficacy of subcutaneous buprenorphine injections were evaluated in a 24-week, phase 3 study (NCT02357901) in which patients were randomized to one of the following three regimens: six once-monthly buprenorphine 300 mg SQ doses (n=196); two once-monthly buprenorphine 300 mg SQ doses followed by four once-monthly 100 mg doses (n=194); or six once-monthly injections of placebo (n=99). Prior to the first dose, treatment was initiated with buprenorphine/naloxone sublingual film and doses were adjusted over 7 to 14 days, and then discontinued for the remainder of the study.

Both dosage regimens of buprenorphine were shown to be superior to placebo in achieving more illicit opioid-free weeks ($p<0.0001$). The proportion of patients achieving treatment success (defined as patients with ≥ 80% opioid-free weeks) was significantly higher in groups receiving buprenorphine compared to placebo (29.1% (300 mg/300 mg), 28.4% (300 mg/100 mg), 2% (placebo)). The overall safety profile for buprenorphine SQ given by a healthcare provider was consistent with the known safety profile of transmucosal buprenorphine, except for injection site reactions. The most common adverse reactions (≥5% patients), included constipation, nausea, vomiting, abnormal liver enzymes, headache, sedation and somnolence. Injection site reactions were reported in 16.5% of the patients. None of the injection site reactions were serious and only one led to study treatment discontinuation.

In May 2023, the FDA approved a second formulation of buprenorphine extended-release injection for subcutaneous use (Brixadi). Brixadi was approved through the 505(b)(2) pathway.

POSITION STATEMENT:

Buprenorphine hydrochloride (Probuphine) subdermal implant:

Buprenorphine hydrochloride (Probuphine) subdermal implant is **not considered a medical necessity** for use beyond two lifetime treatments. A single lifetime treatment consists of four subdermal implants inserted into an arm for six months. Use of fewer than four implants during a treatment cycle (or if implants are removed prior to completion of a six-month treatment cycle) is still considered a single lifetime treatment.

Initiation of buprenorphine hydrochloride (Probuphine) subdermal implant meets the definition of **medical necessity** when **ALL** of the following criteria are met:

1. Prescriber is certified by the PROBUPHINE REMS Program (www.PROBUPHINEREMS.com).
2. Member is diagnosed with opioid dependence – documentation (i.e., clinical notes) from medical record must be provided.
3. Member is compliant with routine urine drug screening (minimum of every 60 days) – laboratory documentation must be provided.

4. Member meets **ONE** of the following:
    a. Compliant with substance abuse counseling – documentation (e.g., chart note, current treatment plan) must be provided.
    b. Treated with buprenorphine or buprenorphine/naloxone for at least two continuous years – documentation (e.g., chart note) must be provided.
5. Member is currently treated with buprenorphine or buprenorphine/naloxone AND has achieved and sustained prolonged clinical stability with current treatment – documentation (i.e., clinical notes) from medical record must be provided.
6. Member's current buprenorphine or buprenorphine/naloxone dose does not exceed any of the following:
    a. Subutex (buprenorphine) sublingual tablet (generic equivalent) 8 mg or less.
    b. Suboxone (buprenorphine and naloxone) sublingual tablet (generic equivalent) 8 mg/2 mg or less.
    c. Bunavail (buprenorphine and naloxone) buccal film 4.2 mg/0.7 mg or less.
    d. Zubsolv (buprenorphine and naloxone) sublingual tablets 5.7 mg/1.4 mg or less.
7. Prescriber confirms that the patient is not diverting buprenorphine or buprenorphine/naloxone, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable.
8. Buprenorphine implant will not be used in combination with another buprenorphine or buprenorphine/naloxone product.
9. Member has not previously been treated with buprenorphine hydrochloride implant OR has only received 1 lifetime treatment consisting of 4 or fewer buprenorphine hydrochloride implants.
10. Dose does not exceed 4 implants per six-month period.

Approval duration: 6 months

Continuation of buprenorphine hydrochloride (Probuphine) subdermal implant meets the definition of **medical necessity** for members meeting the following criteria:

1. Authorization/reauthorization has been previously approved by Florida Blue or another health plan in the past two years for opioid dependence, OR the member has previously met all indication-specific initiation criteria.
2. Prescriber is certified by the PROBUPHINE REMS Program (www.PROBUPHINEREMS.com).
3. Member is diagnosed with opioid dependence – documentation (i.e., clinical notes) from medical record must be provided.
4. Member is compliant with routine urine drug screening (minimum of every 60 days) – laboratory documentation must be provided.
5. Member meets **ONE** of the following:
    a. Compliant with substance abuse counseling – documentation (e.g., chart note, current treatment plan) must be provided.

b. Treated with buprenorphine or buprenorphine/naloxone for at least two continuous years – documentation (e.g., chart note) must be provided.

6. Prescriber confirms that the patient is not diverting buprenorphine or buprenorphine/naloxone, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable.
7. Buprenorphine implant will not be used in combination with another buprenorphine or buprenorphine/naloxone product.
8. Member has received 1 lifetime treatment consisting of 4 or fewer buprenorphine hydrochloride implants.
9. Dose does not exceed 4 implants per six-month period.

Approval duration: 6 months

Buprenorphine (Sublocade) Subcutaneous Injection:

Initiation of buprenorphine (Sublocade) subcutaneous injection **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. Dispensing pharmacy (or healthcare setting) is certified by the SUBLOCADE REMS Program (www.SUBLOCADEREMS.com) and Sublocade will not be dispensed directly to the member.
2. Member is diagnosed with opioid dependence – documentation (i.e., clinical notes) from medical record must be provided.
3. Member is compliant with routine urine drug screening (minimum of every 60 days) – laboratory documentation must be provided.
4. Member meets **ONE** of the following:
    a. Compliant with substance abuse counseling – documentation (e.g., chart note, current treatment plan) must be provided.
    b. Treated with buprenorphine or buprenorphine/naloxone for at least two continuous years – documentation (e.g., chart note) must be provided.
5. Member is currently treated with transmucosal buprenorphine or buprenorphine/naloxone AND has received for a minimum of 7 days – documentation (i.e., clinical notes) from medical record must be provided.
6. Prescriber confirms that the patient is not diverting buprenorphine or buprenorphine/naloxone, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable.
7. Buprenorphine injection will not be used in combination with another buprenorphine or buprenorphine/naloxone product.
8. Dose does not exceed:
    a. Initial: 300 mg monthly x 2 doses (Q9992)
    b. Maintenance: 100 mg monthly (Q9991)

Approval duration:

- Initial: 2 months
- Maintenance: 6 months thereafter

Continuation of buprenorphine (Sublocade) subcutaneous injection **meets the definition of medical necessity** for members meeting the following criteria:

1. Authorization/reauthorization has been previously approved by Florida Blue or another health plan in the past two years for opioid dependence, OR the member has previously met all indication-specific initiation criteria.
2. Dispensing pharmacy (or healthcare setting) is certified by the SUBLOCADE REMS Program (www.SUBLOCADEREMS.com) and Sublocade will not be dispensed directly to the member.
3. Member is diagnosed with opioid dependence – documentation (i.e., clinical notes) from medical record must be provided.
4. Member is compliant with routine urine drug screening (minimum of every 60 days) – laboratory documentation must be provided.
5. Member meets **ONE** of the following:
    a. Compliant with substance abuse counseling – documentation (e.g., chart note, current treatment plan) must be provided.
    b. Treated with buprenorphine or buprenorphine/naloxone for at least two continuous years – documentation (e.g., chart note) must be provided.
6. Prescriber confirms that the patient is not diverting buprenorphine or buprenorphine/naloxone, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable.
7. Buprenorphine injection will not be used in combination with another buprenorphine or buprenorphine/naloxone product.
8. Dose does not exceed 100 mg monthly with the following exception:
    a. Member tolerates 100 mg monthly dose, but does not demonstrate a satisfactory clinical response as evidenced by self-reported illicit opioid use or urine drug screens positive for illicit opioid use – documentation from the medical record must be provided.

Approval duration: 6 months

Buprenorphine (Brixadi) Subcutaneous Injection:

Initiation of buprenorphine (Brixadi) subcutaneous injection **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. Dispensing pharmacy (or healthcare setting) is certified by the BRIXADI REMS Program (www.BRIXADIREMS.com) and Brixadi will not be dispensed directly to the member
2. Member is diagnosed with opioid dependence – documentation (i.e., clinical notes) from medical record must be provided

3. Member is compliant with routine urine drug screening (minimum of every 60 days) – laboratory documentation must be provided
4. Member meets **ONE** of the following:
    a. Compliant with substance abuse counseling – documentation (e.g., chart note, current treatment plan) must be provided
    b. Treated with buprenorphine or buprenorphine/naloxone for at least two continuous years – documentation (e.g., chart note) must be provided
5. Member is currently treated with transmucosal buprenorphine or buprenorphine/naloxone – documentation (i.e., clinical notes) from medical record must be provided
6. Prescriber confirms that the patient is not diverting buprenorphine or buprenorphine/naloxone, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable
7. Buprenorphine injection will not be used in combination with another buprenorphine or buprenorphine/naloxone product
8. Dose does not exceed:
    a. Brixadi (weekly): 32 mg
    b. Brixadi (monthly): 128 mg

Approval duration: 6 months

Continuation of buprenorphine (Brixadi) subcutaneous injection **meets the definition of medical necessity** for members meeting the following criteria:

1. Authorization/reauthorization has been previously approved by Florida Blue or another health plan in the past two years for opioid dependence, OR the member has previously met all indication-specific initiation criteria
2. Dispensing pharmacy (or healthcare setting) is certified by the BRIXADI REMS Program (www.BRIXADIREMS.com) and Brixadi will not be dispensed directly to the member
3. Member is diagnosed with opioid dependence – documentation (i.e., clinical notes) from medical record must be provided
4. Member is compliant with routine urine drug screening (minimum of every 60 days) – laboratory documentation must be provided
5. Member meets **ONE** of the following:
    a. Compliant with substance abuse counseling – documentation (e.g., chart note, current treatment plan) must be provided
    b. Treated with buprenorphine or buprenorphine/naloxone for at least two continuous years – documentation (e.g., chart note) must be provided
6. Prescriber confirms that the patient is not diverting buprenorphine or buprenorphine/naloxone, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable

7. Buprenorphine injection will not be used in combination with another buprenorphine or buprenorphine/naloxone product
8. Dose does not exceed:
    a. Brixadi (weekly): 32 mg
    b. Brixadi (monthly): 128 mg

Approval duration: 6 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- Prescription use of this product is limited under the Drug Addiction Treatment Act
- Probuphine
    - Four implants are inserted subdermally in the upper arm for 6 months of treatment and are removed by the end of the sixth month
    - Implants should not be used for additional treatment cycles after one insertion in each upper arm
    - Implants must be inserted and removed by trained Healthcare Providers only
    - Implants should be administered in patients who have achieved and sustained prolonged clinical stability on transmucosal buprenorphine
    - Examine the insertion site one week following insertion of PROBUPHINE implants for signs of infection or other problems
- Sublocade
    - Injection should only be prepared and administered by a healthcare provider
    - Administered monthly only by subcutaneous injection in the abdominal region
    - Recommended dose is two monthly initial doses of 300 mg followed by 100 mg monthly maintenance doses
    - Dose may be titrated to 300 mg monthly if needed
- Brixadi
    - BRIXADI exists in two formulations.

- Doses of BRIXADI (weekly) cannot be combined to yield a monthly dose.
- Only healthcare providers should prepare and administer BRIXADI.
- Administer BRIXADI as a single injection. Do not divide.
- BRIXADI should be injected slowly, into the subcutaneous tissue of the buttock, thigh, abdomen, or upper arm.
- BRIXADI (weekly) should be administered in 7-day intervals.
- BRIXADI (monthly) should be administered in 28-day intervals.
- For patients not currently receiving buprenorphine treatment, begin with a test dose of 4 mg transmucosal buprenorphine to establish that buprenorphine is tolerated without precipitated withdrawal, and then transition to BRIXADI (weekly). Initiating treatment with BRIXADI as the first buprenorphine product has not been studied. Initiating treatment with BRIXADI (monthly) in new entrants to treatment has not been studied
- See prescribing information for detailed dosing information: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5d8a8fd0-8619-422a-a664-d1d2e8970f48

Dose Adjustments

None

Drug Availability

- Probuphine – 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)
- Sublocade – injection of 100 mg/0.5 mL and 300 mg/1.5 mL provided in a prefilled syringe
- BRIXADI is a weekly and monthly injection provided in a pre-filled single-dose syringe with a 23 gauge ½ inch needle
  - BRIXADI (weekly) is available in 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, and 32 mg/0.64 mL;
  - BRIXADI (monthly) is available in 64 mg/0.18 mL, 96 mg/0.27 mL, and 128 mg/0.36 mL.

PRECAUTIONS:

Boxed Warning

- Probuphine
  - Insertion and removal of implants are associated with the risk of implant migration, protrusion, expulsion, and nerve damage resulting from the procedure.
  - Available only through a restricted program called the PROBUPHINE REMS Program
- Sublocade

    - Risk of serious harm or death with IV administration
    - Available only through a restricted program called the SUBLOCADE REMS Program
- Brixadi
    - Serious harm or death could result if administered intravenously.
    - BRIXADI is only available through a restricted program called the BRIXADI REMS. Healthcare settings and pharmacies that order and dispense BRIXADI must be certified in this program and comply with the REMS requirements

Contraindications

- Probuphine
    - Hypersensitivity to buprenorphine or any other ingredients
- Sublocade
    - Should not be administered to patients who have been shown to be hypersensitive to buprenorphine or any component of the ATRIGEL® delivery system
- Brixadi
    - Hypersensitivity to buprenorphine or any other ingredients in BRIXADI

Precautions/Warnings

- Serious Complications from Insertion and Removal: Rare but serious 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 on the insertion and removal procedures and become certified in the appropriate REMS program, prior to performing insertions or prescribing
- Addiction, Abuse, and Misuse: Buprenorphine can be abused in a manner similar to other opioids. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors
- Respiratory Depression: Significant respiratory depression and death have occurred in association with buprenorphine particularly when taken by the intravenous (IV) route in combination with benzodiazepines or other CNS depressants (including alcohol). Consider dose reduction of CNS depressants when used concomitantly
- Neonatal Opioid Withdrawal Syndrome: Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy
- Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid

- Unintentional Pediatric Exposure: In the event an implant protrudes or comes out, keep the implant away from children. Buprenorphine can cause severe, possibly fatal, respiratory depression in children
- Risk of Opioid Withdrawal with Abrupt Discontinuation: If treatment is temporarily interrupted or discontinued, monitor patients for withdrawal and treat appropriately
- Risk of Hepatitis, Hepatic Events: Monitor liver function tests prior to initiation and during treatment
- Risk of Withdrawal in Patients Dependent on Full Agonist Opioids: Verify that patient is clinically stable on transmucosal buprenorphine and not dependent on full agonists before inserting implant
- Treatment of Emergent Acute Pain: Treat pain with a non-opioid analgesic whenever possible. If opioid therapy is required, monitor patients closely because higher doses may be required for analgesic effect

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J0570	Buprenorphine implant, 74.2 mg [for Probuphine only]
J0577	Injection, buprenorphine extended-release (Brixadi), less than or equal to 7 days of therapy
J0578	Injection, buprenorphine extended-release (Brixadi), greater than 7 days and up to 28 days of therapy
Q9991	Injection, buprenorphine extended release (Sublocade), less than or equal to 100 mg
Q9992	Injection, buprenorphine extended release (Sublocade), greater than 100 mg

ICD-10 Diagnosis Codes That Support Medical Necessity

F11.10	Opioid abuse, uncomplicated
F11.20	Opioid dependence, uncomplicated
F11.21	Opioid dependence, in remission
F11.24	Opioid dependence with opioid-induced mood disorder
F11.250	Opioid dependence with opioid-induced psychotic disorder with delusions
F11.251	Opioid dependence with opioid-induced psychotic disorder with hallucinations
F11.252	Opioid dependence with opioid-induced psychotic disorder unspecified
F11.29	Opioid dependence with other opioid-induced disorder with unspecified opioid-induced disorder

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline revised date.

DEFINITIONS:

Opioid Dependence: a medical diagnosis characterized by an individual's inability to stop using opioids (morphine, heroin, codeine, oxycodone, hydrocodone, etc.) even when objectively it is in his or her best interest to do so.

RELATED GUIDELINES:

None

OTHER:

None

REFERENCES:

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 11/08/23.

GUIDELINE UPDATE INFORMATION:

09/15/16	New Medical Coverage Guideline.
01/01/17	Revision: Added HCPCS code J0570.
10/15/17	Review and revision to guideline, consisting of updating position statement, coding, references.
03/15/18	Revision to guideline; consisting of updating position statement to include Sublocade.
06/15/18	Revision to guideline; consisting of updating position statement
07/01/18	Addition of HCPCS codes Q9991 and Q9992 for Sublocade.
10/15/18	Review and revision to guideline, consisting of updating position statement, coding, references.
11/15/19	Review and revision to guideline, consisting of updating references.
06/15/22	Updated position statement with HCPCS code.
12/15/23	Updated position statement to include Brixadi
01/01/24	Revision: Added HCPCS code J0576 and deleted codes C9154 and J3490.
02/15/24	Revision; updated position statement
04/01/24	Revision: Added HCPCS codes J0577 and J0578 and deleted code J0576.