Pharmacy Medical Necessity Guidelines: Probuphine® and Sublocade™ (buprenorphine)

Effective: May 1, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	PRECERT / MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION (FDA)-APPROVED INDICATIONS

Probuphine (buprenorphine), a partial opioid agonist, is indicated 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 or generic equivalent).

Probuphine (buprenorphine) is not appropriate for new entrants to treatment and patients who have not achieved and sustained prolonged clinical stability, while being maintained on buprenorphine 8 mg per day or less of Subutex or Suboxone sublingual tablet or generic equivalent. Probuphine (buprenorphine) is available as an implant for subdermal administration. Implants must be inserted and removed by trained healthcare providers only. Probuphine (buprenorphine) implants should be administered in patients who have achieved and sustained prolonged clinical stability on transmucosal buprenorphine. Probuphine (buprenorphine) implants should not be used for additional treatment cycles after one insertion in each upper arm.

Sublocade (buprenorphine extended-release), a partial opioid agonist, is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of seven days.

Initiate Sublocade (buprenorphine extended-release) treatment only following induction and dose-adjustment with a transmucosal buprenorphine-containing product. Periodic assessment of the patient is necessary to determine effectiveness of treatment, overall progress, and need for continuation of medication-assisted treatment. There is no maximum recommended duration of maintenance treatment. Sublocade (buprenorphine extended-release) should be administered monthly by healthcare providers via abdominal subcutaneous injection only. Serious harm or death could result if Sublocade (buprenorphine extended-release) is administered intravenously. The injection site should be examined for signs of infection or evidence of tampering or attempts to remove the depot.

Probuphine (buprenorphine) and Sublocade (buprenorphine extended-release) should be used as part of a complete treatment program to include counseling and psychosocial support.

COVERAGE GUIDELINES

The plan may authorize coverage of **Probuphine (buprenorphine)** for Members when all of the following criteria are met:

1. Documented diagnosis of opioid dependence

AND

2. Documentation the Member is clinically stable on doses of buprenorphine of ≤8 mg or equivalent dosed formulation for at least three months

AND

3. Documentation Probuphine (buprenorphine) is used as part of a complete treatment regimen that includes counseling and psychosocial support

The plan may authorization coverage of **Sublocade (buprenorphine)** for Members when all of the following criteria are met:

1. Documented diagnosis of opioid dependence

AND

2. Documentation the Member is clinically stable on doses of buprenorphine of ≤24 mg per day for at least seven days

AND

3. Documentation Sublocade (buprenorphine extended-release) is used as part of a complete treatment regimen that includes counseling and psychosocial support

LIMITATIONS

- Probuphine (buprenorphine) and Sublocade (buprenorphine extended-release) will not be authorized for buprenorphine-naïve Members.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J0570	Buprenorphine implant, 74.2 mg
Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg
Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg

REFERENCES

1. Probuphine (buprenorphine) [package insert]. Princeton, NJ; Braeburn Pharmaceuticals, Inc.: 2016 May.
2. Sublocade (buprenorphine extended-release) [package insert]. North Chesterfield, VA; Indivior Inc.: 2018 March.

APPROVAL HISTORY

November 15, 2016: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2017: Administrative update: added HCPCS code to Medical Necessity Guideline.
2. March 14, 2017: Removed the criterion requiring documentation the prescriber has been granted an "X" DEA number and documentation the provider has completed a live training to insert Probuphine.
3. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
4. June 12, 2018: Changed the title of the Medical Necessity Guideline (MNG) from "Probuphine (buprenorphine)" to "Probuphine and Sublocade (buprenorphine)." Added coverage criteria for Sublocade (buprenorphine extended-release) to the MNG.
5. July 01, 2018: Administrative update: Added new Q Code Q9991 and Q9992 to Medical Necessity Guideline.
6. March 12, 2019: No changes.
7. April 14, 2020: Effective May 1, 2020, retire Medical Necessity Guideline for Tufts Health Plan Commercial Products (including Tufts Health Freedom) and Tufts Health Direct. Effective May 1, 2020 for Tufts Health Together and Tufts Health RITogether, removed reauthorization criteria. Updated coverage criteria to require appropriate diagnosis, documentation of clinical stability on the recommended dose of buprenorphine or equivalent dosage form per package labeling, and documentation the requested agent will be used as part of a complete treatment regimen that

includes counseling and psychosocial support. Removed the following Limitations: "Sublocade (buprenorphine extended-release) will not be authorized if there are signs of infection at the injection site, evidence of tampering with the depot, or attempts to remove the depot."

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.