

<b>Policy Title:</b>	Probuphine (buprenorphine implant) (Implant)		
		<b>Department:</b>	PHA
<b>Effective Date:</b>	01/01/2020		
<b>Review Date:</b>	12/20/2019, 1/22/20, 2/04/2021, 2/24/2022, 12/07/2023, 01/04/2024		

**Purpose:** To support safe, effective and appropriate use of Probuphine (buprenorphine implant).

**Scope:** Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

**Policy Statement:**

Probuphine (buprenorphine implant) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

**Procedure:**

Coverage of Probuphine (buprenorphine implant) will be reviewed prospectively via the prior authorization process based on criteria below.

**Initial Criteria:**

- Documentation of the member’s requirement for maintenance treatment of opioid dependence; AND
- Documentation of clinical stability on a transmucosal buprenorphine-containing product such as Suboxone, Subutex or generic equivalent; AND
- Documentation of clinical stability as defined by the following:
  - No reports of any illicit opioid use
  - No reports of significant withdrawal symptoms
  - Reports of low to no desire/need to use illicit opioids
  - No episodes of hospitalizations (addiction or mental health issues), emergency room visits, or crisis interventions in the past 90 days
  - Stable living environment, participation in a structured activity/job that contributes to the community, consistent participation in recommended cognitive behavioral therapy/peer support program
  - Consistent compliance with clinic visit requirement; AND
- The member has been clinically stable for at least 3 months on a transmucosal buprenorphine containing product without any need for supplemental dosing or dose adjustment; AND
- The member is a new start on Probuphine or has received one previous 6-month course of Probuphine (maximum of 1 insertion); AND

- The member is clinically stable on a maintenance dose of a transmucosal buprenorphine containing product that does not exceed the following:

<b>Transmucosal Buprenorphine-Containing Product</b>	<b>Maximum Maintenance Dose (Prior to Starting Probuphine)</b>
Buprenorphine sublingual tablet (generic Subutex)	8 mg per day
Buprenorphine/naloxone sublingual tablet (generic Suboxone sublingual tablets) Suboxone sublingual film	8 mg / 2 mg per day
Zubsolv sublingual tablet	5.7 mg / 1.4 mg per day
Bunavail buccal film	4.2 mg / 0.7 mg per day

- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

***Continuation of Therapy Criteria:***

- Patient continues to meet all initial criteria and patient is tolerating treatment; AND
- The patient has sustained clinical stability on Probuphine; AND
- The member has not already received a maximum of two 6-month cycles of Probuphine (maximum of 2 insertions) in a one-year period

**Coverage durations:**

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

**Dosage/Administration:**

<b>Indication</b>	<b>Dose</b>	<b>Maximum dose (1 billable unit = 74.2mg)</b>
opioid dependence	74.2mg implanted every 6 months	74.2mg implanted every 6 months

**Investigational use:** All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

**Applicable Codes:**

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0570	Buprenorphine implant, 74.2mg

References:

1. Probuphine [package insert]. Princeton, NJ: Braeburn Pharmaceuticals, Inc. October 2020.