Policy Title:	Probuphine (buprenorphine implant) (Implant)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	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.

Summary of Evidence:

Probuphine 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. A phase 3 trial evaluated the efficacy and safety of Probuphine in adults with opioid dependence who were stable on transmucosal buprenorphine at doses of 8 mg/day or less. The trial demonstrated that Probuphine was non-inferior to sublingual buprenorphine-naloxone in maintaining opioid abstinence over 24 weeks. Patients receiving Probuphine experienced significantly fewer self-reported opioid use days compared to those on sublingual buprenorphine-naloxone. Probuphine has been shown to improve treatment adherence and reduce the risk of diversion or accidental exposure to buprenorphine-containing products compared to daily oral formulations. The implantable nature of Probuphine provides continuous delivery of buprenorphine over a six-month period, which may enhance patient convenience and treatment adherence.

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 exceed the following:

Transmucosal Buprenorphine-Containing Product	**Maximum Maintenance Dose (Prior to Starting Probuphine)**
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).

Policy Rationale:
Probuphine was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Probuphine according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = 74.2mg)**
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.