Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MBP 146.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Probuphine (buprenorphine)

I. Policy:
Probuphine (buprenorphine)

II. Purpose/Objective:
To provide a policy of coverage regarding Probuphine (buprenorphine)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:
Probuphine (buprenorphine) is a partial opioid agonist 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

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Probuphine (buprenorphine) will be considered medically necessary when ALL of the following criteria are met:

- Prescriber must have a unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine agents **AND**
- Prescriber must have enrolled, trained, and demonstrated competency in Probuphine procedures as described by the Probuphine REMS Program **AND**
- Medical record documentation of a diagnosis of opioid dependence **AND**
- Medical record documentation that patient is clinically stable by verifying **ALL** of the following:
    - No reports of significant withdrawal symptoms
    - Reports of low to no desire/need to use illicit opioids
    - No episodes of hospitalizations (for addiction or mental health issues), emergency room visits, or crisis interventions in the past 90 days
    - Consistent compliance with clinic visit requirements as evidenced by documentation of attendence to all scheduled appointments **at least** 6 months prior to the ordering of Probuphine **AND**
- Medical record documentation that patient is stable for at least the last 6 months 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 tablets or generic equivalent) **AND**
- Medical record documentation that the member is compliant with oral buprenorphine therapy, documented by all urine drug screens within 90 days of the request, one of which must be dated within 28 days of request date, for opiates and buprenorphine. The drug screen must be positive for buprenorphine and norbuprenorphine and negative for opiates. The presence of other non-opiate controlled substances must be consistent with prescribed controlled substances and documentation that their use is medically necessary and the benefit outweighs any risks associated with their use in the member must be provided. **AND**
- Medical record documentation that the member will not be receiving supplemental sublingual buprenorphine after implant insertion **AND**
- There is confirmation that the prescriber or the prescriber's delegate has conducted a review of Pennsylvania's Prescription Drug Monitoring Program (PDMP) prior to prescribing Probuphine.

  For re-authorization:
    - Medical record documentation that Probuphine has **NOT** been used for greater than one year **AND**
    - Medical record documentation that the new implants will be inserted into the contralateral arm **AND**
    - Medical record documentation that member will not be receiving supplemental sublingual buprenorphine after implant insertion **AND**
    - There is confirmation that the prescriber or the prescriber's delegate has conducted a review of Pennsylvania's Prescription Drug Monitoring Program (PDMP) prior to prescribing Probuphine.

QUANTITY LIMIT: Four (4) implants (one kit) every 180 days

AUTHORIZATION DURATION: If approved, initial authorization duration will be six (6) months. After the initial 6 month implantation, if re-authorization criteria are met, one subsequent authorization duration will be given for six (6) months. Note: studies of Probuphine use past one year have not be assessed.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 11/15/16

Revised: 7/17/18 (PDMP), 8/23/18 (per DHS)

Reviewed: 10/31/17