Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Probuphine (buprenorphine)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***July 2016***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Probuphine (buprenorphine)

Probuphine (buprenorphine) 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 (doses no more than 8mg per day of Subutex or Suboxone sublingual tablet equivalent or generic equivalent). Probuphine should be used as part of a complete treatment program to include counseling and psychosocial support. Probuphine is not appropriate for new entrants to treatment and patients who have not achieved and sustained prolonged clinical stability, while being maintained on buprenorphine 8mg per day or less of Subutex or Suboxone sublingual tablet equivalent or generic equivalent.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Probuphine (buprenorphine), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must have a diagnosis of opioid dependence
- Must be stable on no more than 8mg per day of sublingual buprenorphine for at least the last 6 months
- Prescriber must attest to the member's clinical stability based on the following factors:
    - 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 hospitalizations, emergency room visits, or crisis intervention in the past 90 days (for addiction or mental health issues)
    - Stable living environment, participation in a structured job/activity that contributes to the community, consistent participation in recommended cognitive behavioral therapy/peer support program
    - Consistent adherence with clinic visit requirements
- Must have chart documentation of a urine/substance drug screen within the last 3 months that documents all of the following:
    - Positive for buprenorphine
    - Negative for licit and illicit drugs with the potential for serious abuse
        - Must include testing for oxycodone and methadone
        - Must be consistent with prescribed controlled substances
        - No evidence of heavy or frequent alcohol consumption
- Must have chart documentation showing participation of at least monthly formal behavioral health counseling, substance abuse counseling, or an addiction recovery program
- Must not have attempted to fill any opioid prescriptions or benzodiazepines as indicated by the drug claim history

- Must not be receiving supplemental sublingual buprenorphine after implant insertion
- Must be prescribed by prescriber who has unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine and must be certified by the Probuphine REMSprogram
- Must be implanted by a healthcare provider who is certified by the phine MS program

Reauthorization Criteria:

All prior authorization renewals are reviewed on a 6 month basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6-month intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy and the following:

- Must not be receiving supplemental sublingual buprenorphine
- Must have chart documentation of a urine/substance drug screen within the last 3 months that documents all of the following:
    - Positive for buprenorphine
    - Negative for licit and illicit drugs with the potential for serious abuse
        - Must include testing for oxycodone and methadone
        - Must be consistent with prescribed controlled substances
        - No evidence of heavy or frequent alcohol consumption
- Must have chart documentation showing participation of at least monthly formal behavioral health counseling, substance abuse counseling, or an addiction recovery program.
- Must not have attempted to fill any opioid prescriptions or benzodiazepines as indicated by the drug claim history
- Must be prescribed by prescriber who has unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine and must be certified by the Probuphine REMSprogram
- Must be implanted by a healthcare provider who is certified by the Probuphine REMS program
- Implant must not be inserted into a site which was previously used for insertion

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Same as initial
Quantity Level Limit	
Probuphine	4 implants per 6 months

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Probuphine [prescribing information]. Princeton, NJ: Braeburn Pharmaceuticals, Inc. May 2016.
2. Probuphine (buprenorphine HCl) Implant CIII Treatment of Opioid Dependence: Briefing Document For the FDA Advisory Committee Meeting. Braeburn Pharmaceuticals. fda.gov. Prepared Dec 11, 2015. Available from: http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/psychopharmacologicdrugsadvisorycommittee/ucm480733.pdf. Accessed 5/31/2016
3. Probuphine (Buprenorphine Hydrochloride Implant) Psychopharmacologic Drugs Advisory Committee [PowerPoint slides]. Braeburn Pharmaceuticals. Presented January 12, 2016. Retrieved 05/31/2016.
4. Center for Substance Abuse Treatment. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol(TIP) Series 40. DHHS Publication No. (SMA)04-3939. Rockville, MD: Substance Abuse and Mental Health Services

Administration, 2004.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*2/17, 02/18*