Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE:	**Buprenorphine/Naloxone (Bunavavail, Suboxone, Zubsolv) and Buprenorphine (Subtex)**
DEPARTMENT:	**Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE:	***March 2008 (as adopted from UPMC Health Plan)***

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 buprenorphine/naloxone (Bunavail, Suboxone, Zubsolv) and buprenorphine (Subutex).

Buprenorphine/naloxone (Bunavail, Suboxone, Zubsolv) and buprenorphine (Subutex) are indicated for the treatment of opioid dependence.

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, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drugs, buprenorphine/naloxone (Bunavail, Suboxone, Zubsolv) and buprenorphine

(Subutex), are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

For All Diagnoses:

- Must have a diagnosis of opioid dependence
- Must have an initial urine drug screen within the last 3 months which is consistent with a diagnosis of opioid dependence. Documentation of the recent drug test must be provided.
- Must have documentation of an initial evaluation or scheduled appointment by a licensed Drug & Alcohol provider to determine the recommended level of care
- Must have documentation of referral to or enrollment in formal behavioral health counseling and/or substance abuse counseling. Initial treatment must be performed with a licensed Drug and Alcohol (D & A) or a behavioral health provider that is consistent with the level of care recommended at the initial evaluation.
- Must not have attempted to fill any opioid prescriptions during this initial period as indicated by their drug claim history
- Benzodiazepines are covered for the initial approval period to allow time to taper benzodiazepine therapy.
    - Tapering is not required for members that meet the following:
        - Concurrent use of buprenorphine and a benzodiazepine is medically necessary
            - For patients using benzodiazepines for anxiety or insomnia: documentation of a trial of other treatment options or clinical rationale for why other treatment options cannot be used must be provided
        - The patient has been counseled on the risk associated with concurrent use and will be monitored
- Must be prescribed by a prescriber who has a unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine

For Commercial members: if the above criteria are met, buprenorphine/naloxone **tablet** or **film** product (Suboxone Tablet, Suboxone Film, Zubsolv Tablet, or Bunavail Film) is approved for:

- 3 months for members who are referred to or have a D&A appointment scheduled but have not yet been evaluated
- 6 months for members who have been evaluated by a D&A provider which indicates the recommended level of care and have begun treatment in a licensed drug and alcohol program

In addition to the above criteria, an exception for the buprenorphine-only product (Subutex) can be made for one of the following two reasons:

1. The member is pregnant.
2. The member has documented intolerance to naloxone.

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 provider that the member's condition has improved based upon the prescriber's assessment while on therapy. In addition, for continuation:

- Must have a diagnosis of opioid dependence
- Must be compliant with therapy for the previous approval duration (3 or 6 months) as evidenced in the member's pharmacy claim history showing that the member has received some level of continuous therapy. A call is placed to the prescriber to determine the current dose regimen if necessary. (All non-compliance issues are forwarded to a Medical Director for review).
- Must have chart documentation of a recent quarterly urine drug screen that documents all of the following:
    - Positive for buprenorphine
    - Testing for licit and illicit drugs with the potential for abuse and oxycodone that is consistent for prescribed controlled substances
- Must be participating in counseling as follows:
    - For members approved initially for 3 months (1st reauthorization only):
        - Must have chart documentation confirming completion of evaluation with a licensed D&A provider which indicates the recommended level of care and have begun treatment in a licensed drug and alcohol treatment program.
        - Must have chart documentation showing participation in formal behavioral health counseling and/or substance abuse counseling that is consistent with the level of care recommended at the initial evaluation
    - For members approved previously for 6 months:

        - Must have documentation of participation with a licensed D&A provider at the recommended level of care until completion of the program
        - Must have chart documentation showing participation of at least monthly formal behavioral health counseling, substance abuse counseling, or an addiction recovery program or must be participating in formal behavioral health counseling or an addiction recovery program as indicated in the initial D&A evaluation. After a period of 1 year, less formal programs would be allowed as participation.

- Must not have attempted to fill any opioid prescriptions or benzodiazepines during this authorization period as indicated by the drug claim history
    - Concurrent benzodiazepine use is allowed if all of the following are met:
        - Concurrent use of buprenorphine and a benzodiazepine is medically necessary
            - For patients using benzodiazepines for anxiety or insomnia: documentation of a trial of other treatment options or clinical rationale for why other treatment options cannot be used must be provided
        - The patient has been counseled on the risk associated with concurrent use and will be monitored

- Must be prescribed by a prescriber who has a unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine

For Commercial members: if the above criteria are met, buprenorphine/naloxone **tablet** or **film** product (Suboxone Tablet, Suboxone Film, Zubsolv Tablet, or Bunavail Film) is approved for 6 months.

In addition to the above criteria, an exception for the buprenorphine-only product (Subutex) can be made for the following two reasons:
1. The member is pregnant **OR**
2. The member has documented intolerance to naloxone

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Case-by-Case biases
Reauthorization	Up to 6 months

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

REFERENCES

1. Suboxone/Subutex [package insert]. Richmond, VA: Reckitt Benckiser Pharmaceuticals, Inc.; February 2017
2. Buprenorphine – About Buprenorphine Therapy. U. S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration-Center for Substance Abuse Treatment, updated 2/28/07; Accessed 8/10/07 at http://buprenorphine.samhsa.gov/about.html
3. Buprenorphine Physician and Treatment Program Locator. U. S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration-Center for Substance Abuse Treatment, updated 2/28/07; Accessed 8/10/07 at http://www.buprenorphine.samhsa.gov/bwns_locator/index.html
1. *Proprietary and Confidential Information of Evolent Health LLC © 2015 Evolent Health LLC All Rights Reserved*
4. Buprenorphine – Report of the Center for Substance Abuse Work Group, Federation of State Medical Boards of the United States, Inc., updated 2/28/07; Accessed 8/13/07 at http://buprenorphine.samhsa.gov/model.html
5. Suboxone and Pregnancy – What You Need to Know. American Society of Addiction Medicine, buprenorphine CME program, updated 2007; Accessed 8/10/07 at http://images1.clinicaltools.com/images/cmeopiate/06specpop-handoutp1.pdf
6. Zubsolv [package insert]. New York, NY: Orexo US, Inc.; July 2013
7. Bunavail [package insert]. Raleigh, NC: BioDelivery Sciences. June 2014.

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	*02/16, 02/17, 02/18*
Criteria Update	*11/17*