Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MBP 176.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Sublocade (buprenorphine ER subcutaneous injection)

I. Policy:
Sublocade (buprenorphine ER subcutaneous injection)

II. Purpose/Objective:
To provide a policy of coverage regarding Sublocade (buprenorphine ER subcutaneous injection)

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:
Sublocade (buprenorphine ER subcutaneous injection) is a subcutaneously administered, long-acting buprenorphine product. Buprenorphine exerts its analgesic effect via high-affinity binding to mu opiate receptors in the CNS; displays partial mu agonist and weak kappa antagonist activity. Due to it being a partial mu agonist, its analgesic effects plateau at higher doses and it then behaves like an antagonist. The extended-release formulation is injected subcutaneously as a liquid; subsequent precipitation following injection results in a solid depot which will gradually release buprenorphine via diffusion and biodegradation of the depot.

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

Sublocade (buprenorphine ER subcutaneous injection) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of opioid use disorder (opioid dependence) **AND**
- Medical record documentation that member has been initiated into treatment with a transmucosal buprenorphine-containing product (e.g. Suboxone, buprenorphine/naloxone, buprenorphine), followed by dose adjustment for a minimum of 7 days AND until cravings and withdrawal symptoms are clinically controlled **AND**
- Medical record documentation that the member will not be receiving supplemental sublingual buprenorphine concurrently with Sublocade **AND**
- If the member has previously been established on Sublocade and the 300mg maintenance dose is requested: Medical record documentation that the member has tried and failed the 100mg maintenance dose AND that the benefits outweigh the risks of increasing to the 300mg maintenance dose **AND**
- Confirmation that the prescriber or prescriber's delegate has conducted a review of Pennsylvania's Prescription Drug Monitoring Program (PA PDMP) prior to administering Sublocade.

AUTHORIZATION DURATION: If approved, initial authorization duration will be for 3 months. After the initial 3-month authorization, subsequent approval will be for 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Medical record documentation that the member will not be receiving supplemental sublingual buprenorphine concurrently with Sublocade **AND**
- Medical record documentation of one of the following:
    - That the member will continue to receive the 100mg monthly maintenance dose **OR**
    - If 300mg maintenance dose is requested, the member has tried and failed the 100mg monthly maintenance dose AND the benefits outweigh the risks of receiving the 300mg monthly dose

  AND
- Confirmation that the prescriber or prescriber's delegate has conducted a review of Pennsylvania's Prescription Drug Monitoring Program (PA PDMP) prior to administering Sublocade.

QUANTITY LIMIT:

- For 100mg dose: 1 syringe (0.5mL) per 28 days
- For 300mg dose: 1 syringe (1.5mL) per 28 days

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: 5/15/18

Revised: 8/9/18 (per DHS requirements)

Reviewed: