Clinical Policy: Buprenorphine and Buprenorphine/Naloxone Approval Criteria for MAT

Reference Number: IN.CP.PMN.81
Effective Date: 12.17
Last Review Date: 10.22
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The purpose of this Policy is to provide criteria for the approval of non-preferred buprenorphine and buprenorphine/naloxone for the use in medication assisted treatment (MAT) for opioid use disorder.

Override	Approval Duration
Prior Authorization	Brand BUPRENORPHINE/NALOXONE agents will be approved for up to 12 months; may dispense up to a 30-day supply at a time only

Medication	Status	Strength	Quantity Limit
Suboxone Film (and generically available film formulation)	Preferred only for pregnancy	2mg – 0.5mg 4mg – 1mg 8mg – 2mg	3 film per day 3 film per day 3 films per day

FDA Approved Indication(s)

All edits are based on FDA labeling as published by the manufacturer

Brand

Multiple Medication classes are included in this edit

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Requests for a non-preferred brand buprenorphine/naloxone agent may be approved if the following criteria are met:

I. All of the following:

a. The individual has failed an adequate trial of the preferred generic buprenorphine/naloxone agent within the previous 120 days (**Note**: Adequate trial is defined as at least 28 days of treatment.); **AND**
b. One of the following:
1) The patient experienced therapeutic failure with the preferred generic buprenorphine/naloxone agent (**Note:** brand buprenorphine agents will not be approved for patients who report lesser efficacy as compared to the preferred generic buprenorphine agent unless it would be clinically inappropriate to address efficacy with dose adjustment.); **OR**
2) Generics caused adverse outcome; **AND**
c. The prescriber has provided confirmation of a MedWatch form submission to the FDA documenting the therapeutic failure or adverse outcome experienced by the patient. (**Note**: The MedWatch form is available at https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf)

OR

II. Both of the following:
a. The individual has a hypersensitivity reaction to an inactive ingredient in the preferred generic buprenorphine agent(s); **AND**
b. The hypersensitivity reaction(s) is clearly documented in the patient's medical record.
OR

III. Both of the following:
a. The individual has a confirmed pregnancy; **AND**
b. Request is for buprenorphine-naloxone film

Additional Notes:

- GI upset or irritation is not generally considered an allergy or failed treatment. Patients should be referred to their physician or pharmacist for advice on dose adjustment, and/or other options to reduce GI upset/irritation.
- Common documented side effects attributed to the drug (i.e. headache, nausea, blurred vision, fatigue, muscle aches) are not considered an allergy and would be expected to occur at the same level in both the generic and brand agent.
- Drug hypersensitivity symptoms may include skin rash, hives, itching, fever, swelling, shortness of breath, wheezing, runny nose, itchy and/or watery eyes, and in severe cases, anaphylaxis.

RATIONALE
The intent of this prior authorization criteria is to encourage the use of cost-effective preferred generic medications before considering coverage of brand medications.

REFERENCES:
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available at http://www.fda.gov/safety/medwatch/default.htm. Accessed November 13, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Revised dispense max to 30 day supply Added generic buprenorphine/naloxone film to non-preferred guideline	10/2018	10/2018
Annual Review – No changes	10/2019	10/2019
Removed Zubsolv and Bunavail; added pregnancy criteria	07/28/2020	
Annual Review: No changes	10/14/2020	10/14/2020
Annual Review – No changes	10/2022	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.