POLICY AND PROCEDURE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Buprenorphine and Buprenorphine/Naloxone Approval Criteria for MAT
PAGE: 1 of	**REPLACES DOCUMENT:**
APPROVED DATE: 10/2017	**RETIRED:**
EFFECTIVE DATE: 12/1/2017	**REVIEWED/REVISED:**
PRODUCT TYPE: Medicaid	**REFERENCE NUMBER:** IN.CP.PMN.81

SCOPE:
The MHS Indiana Medicaid business lines, Envolve Pharmacy Solutions.

PURPOSE:
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.

PROCEDURE:

Override	Approval Duration
Prior Authorization	Brand BUPRENORPHINE/NALOXONE agents will be approved for up to 12 months; may dispense up to a 34-day supply at a time only

Medication	Status	Strength	Quantity Limit
Suboxone Film	Non-preferred	2mg – 0.5mg 4mg – 1mg 8mg – 2mg 12mg – 3 mg	1 film per day 1 film per day 2 films per day 2 films per day
Zubsolv	Non-preferred	0.7mg-0.18mg 2.9mg – 0.7mg 11.4mg – 2.9mg 1.4mg – 0.36mg 5.7mg – 1.4mg 8.6mg – 2.1 mg	1 tab per day 1 tab per day 1 tab per day 1 tab per day 1 tab per day 2 tabs per day
Bunavail	Non-preferred	2.1mg – 0.3mg 4.2mg – 0.7mg 6.3mg – 1mg	1 film per day 2 films per day 2 films per day

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.

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.

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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.

ATTACHMENTS:

DEFINITIONS:

REVISION LOG

REVISION	DATE

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in Compliance 360, Centene's P&P management software, is considered equivalent to a physical signature.

Director of Pharmacy_____ Date: _____

Chief Medical Director_____ Date: _____

Plan President & CEO_____ Date: _____