UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2059-10
Program	Prior Authorization/Medical Necessity Buprenorphine/Naloxone Products
Medication	Buprenorphine/naloxone products: Bunavail*and Suboxone * (Brand Only)
P&T Approval Date	7/2015, 10/2016, 3/2017, 9/2017, 9/2018, 7/2019, 7/2020, 11/2020, 11/2021
Effective Date	2/1/2022; Oxford: 2/1/2022

1. Background

Suboxone* and Bunavail* are Schedule III narcotic medications available under the Drug Abuse Treatment Act (DATA) of 2000 for the treatment of opioid dependence. Only qualified doctors with the necessary DEA (Drug Enforcement Agency) identification number can prescribe or dispense buprenorphine products for opioid addiction therapy.

Bunavail* and Suboxone* contain buprenorphine, a schedule III narcotic and naloxone, an opiate antagonist. Buprenorphine, like other opioids has the potential for being abused. Naloxone is used to guard against misuse by blocking the effects of opiates if the drug is manipulated for injection.
This program requires a member to meet treatment criteria prior to the coverage of buprenorphine/naloxone combination products. It also requires the member to try the preferred combination product buprenorphine/naloxone (generic Suboxone) or Zubsolv prior to receiving coverage for Bunavail*, Suboxone *.

2. Coverage Criteria[a, b]:

A. Initial Authorization

1. **Suboxone*** (Brand Only) **or Bunavail*** will be approved based on **both** of the following criteria:

   a. The patient is being treated for opioid dependence

   -AND-

   b. Both of the following:

      i. **One** of the following:

(a) Submission of medical records (e.g. chart notes) documenting an inadequate response to a minimum 30-day trial of Zubsolv. (30-day trial must be completed prior to Prior Authorization/Medical Necessity request.)
(b) Submission of medical records (e.g. chart notes) documenting the member has experienced adverse effects or has a contraindication to Zubsolv, including the manifestation of the adverse reaction or reason for contraindication

-AND-

ii. **One** of the following:

(a) Submission of medical records (e.g. chart notes) documenting an inadequate response to a minimum 30-day trial of buprenorphine/naloxone (generic Suboxone). (30-day trial must be completed prior to Prior Authorization/Medical Necessity request.)
(b) Submission of medical records (e.g. chart notes) documenting the member has experienced adverse effects or has a contraindication to generic buprenorphine/naloxone (generic Suboxone) including the manifestation of the adverse reaction or reason for contraindication

Authorization will be issued for 12 months.

B. Reauthorization:

1. **Suboxone*** (Brand Only) **or Bunavail*** will be approved based on the following criterion:

a. Documentation of positive clinical response

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] Review not required for plans sitused in the state of Illinois.

3. Additional Clinical Rules:

- Supply limits may be in place.
- Bunavail, Suboxone (Brand Only) are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.
  Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Suboxone [package insert]. Richmond, VA: Indivor Inc.; March 2021.
2. 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.
3. Bunavail [package insert]. Raleigh, NC: BioDelivery Sciences International, Inc.; March 2021.

Program	Prior Authorization/Medical Necessity – Buprenorphine/Naloxone Products
Change Control	
Date	Change
7/2015	New Program
10/2016	Annual update. Decreased reauthorization period from 24 months to 12 months. Updated references.
3/2017	Administrative update. Removed requirement for medical record submission to verify opioid dependence diagnosis. Updated references.
9/2017	Changed reference from intolerance to adverse reaction to Zubsolv. Removed DEA waiver requirement.
9/2018	Annual review. Removed reference to brand Suboxone tablets (brand no longer available). Updated references.
7/2019	Removed generic Suboxone and buprenorphine/naloxone tablets from medications covered by criteria. Added criteria for DATA2000 prescriber.
7/2020	Annual review. Updated references. Clarified timing of 30 day trial.
11/2020	Removed criteria for DATA2000 prescriber. Removed pain management confirmation. Updated medical records requirement.
11/2021	Annual review. Updated references.
1/2022	Administrative change. Illinois footnote added. Criteria retired 1/2019 for Illinois.