UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2059-5
Program	Prior Authorization/Medical Necessity Oxford – Buprenorphine/Naloxone Products
Medication	Buprenorphine/naloxone products*: Bunavail*, Suboxone Film*, generic buprenorphine/naloxone*
P&T Approval Date	7/2015, 10/2016, 3/2017, 9/2017, 9/2018
Effective Date	12/1/2018; Oxford: 12/1/2018

1. Background

Suboxone*, Bunavail*, and generic buprenorphine/naloxone* 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*, Suboxone*, and the generic buprenorphine/naloxone* combination contain an opiate antagonist to guard against misuse. Intravenously administered naloxone will block the effect of opiates and cause withdrawal symptoms.

This program requires a member to meet treatment criteria prior to the coverage of buprenorphine or buprenorphine/naloxone combination products. It also requires the member to try the preferred combination product Zubsolv prior to receiving coverage for Bunavail*, Suboxone Film*, or generic buprenorphine/naloxone*.

2. Coverage Criteria:

A. Initial Authorization

1. **Suboxone Film*, Bunavail* and generic buprenorphine/naloxone*** will be approved based on **all** of the following criteria:

   a. The patient is being treated for opioid dependence

   -AND-

   b. The medication is not being used solely for pain management

   -AND-

c. The member is not currently taking opioids

-AND-

d. One of the following:

i. 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 approval.)

-OR-

ii. The member has experienced adverse effects or has a contraindication to Zubsolv. (List manifestation of the adverse reaction or reason for contraindication and the prescriber's expectation for an alternative experience with a non-preferred product)

Authorization will be issued for 12 months.

B. Reauthorization:

1. **Suboxone Film*, Bunavail*, and generic buprenorphine/naloxone*** will be approved based on the following criterion:

a. Documentation of positive clinical response

Authorization will be issued for 12 months.

3. Additional Clinical Rules:
Supply limits may be in place.
* Bunavail, Suboxone Film, and generic buprenorphine/naloxone are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

4. References:

1. Suboxone prescribing information. Richmond, VA. Indivior Inc. February 2018.
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. Buprenorphine hydrochloride and naloxone hydrochloride sublingual tablets prescribing information. Parsippany, NJ. Actavis. February 2018.
4. Bunavail prescribing information. BioDelivery Sciences International, Inc. Raleigh, NC. February 2018.

Program	Prior Authorization/Medical Necessity Oxford – 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.