



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1100-6
Program	Prior Authorization/Notification
Medication	Bunavail™, Suboxone Film® (buprenorphine HCL and naloxone), and generic buprenorphine/naloxone
P&T Approval Date	11/2007, 8/2008, 8/2009, 5/2010, 5/2011, 11/2011, 7/2012, 7/2013, 10/2013, 10/2014, 10/2015, 10/2016, 3/2017, 4/2018
Effective Date	8/1/2018; Oxford only: N/A

1. Background

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

2. Coverage Criteria:

A. Bunavail*, Suboxone Film* (buprenorphine/naloxone), or generic buprenorphine/naloxone* will be approved based on **all** of the following criteria:

1. The physician has been issued a unique DEA identification number, indicating that he/she is a qualified physician under DATA 2000 to prescribe buprenorphine products.

-AND-

2. The patient is being treated for opioid dependence.

-AND-

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

Authorization will be issued for 12 months.

*Bunavail, generic buprenorphine/naloxone and Suboxone Film are typically excluded from coverage. Please refer to plan specifics to determine exclusion status.

3. Additional Clinical Rules:
Supply limits may be in place.

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. October 2017.
4. Bunavail prescribing information. BioDelivery Sciences International, Inc. Raleigh, NC. January 2017.

Program	Prior Authorization/Notification - Bunavail, generic buprenorphine/naloxone, Suboxone Film
Change Control	
Date	Change
7/2013	Reformatted to align with template; background information expanded; updated references
10/2013	Added Zubsolv to criteria. Added criteria that drug is not being used for pain management
10/2014	Added Bunavail to criteria. Noted that Bunavail and Suboxone are typically excluded from coverage. Updated references.
10/2015	Minor wording changes to background section. Added generic buprenorphine/naloxone to the criteria. Added criteria allowing for use of buprenorphine monotherapy in members with moderate or severe hepatic impairment. Provided clarification that products cannot be used solely for pain management. Updated references.
10/2016	Annual review. Updated references.
3/2017	Removed buprenorphine (generic Subutex) and Zubsolv from medications covered by criteria.
4/2018	Annual review. Updated references.