UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Suboxone, Subutex

Program	Prior Authorization
Medication	Suboxone® (buprenorphine/naloxone), buprenorphine sublingual tablet, Zubsolv ® (buprenorphine/naloxone), Bunavail, (buprenorphine/naloxone), buprenorphine/naloxone tablet
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	4/2017
Effective Date	6/2017

1. Background:

FDA Approved Indications

Opioid Dependence: Suboxone, buprenorphine sublingual tablet, Zubsolv, Bunavail, and buprenorphine/naloxone tablet are indicated for the treatment of opioid dependence.

Off-labeled Use:
UnitedHealthcare Community Plan does not cover Suboxone, buprenorphine sublingual tablet, Zubsolv, Bunavail, and buprenorphine/naloxone tablet for off-labeled uses.

Preferred Products:

Preferred Products
Suboxone® (buprenorphine/naloxone sublingual film) 8/2 mg
Suboxone® (buprenorphine/naloxone sublingual film) 2/0.5 mg
Buprenorphine sublingual tablets (generic Subutex)

2. Coverage Criteria:

A. <u>Initial Authorization</u>

1. **Suboxone Film, buprenorphine sublingual tablet, Zubsolv, Bunavail, or buprenorphine/naloxone tablet** will only be approved based on meeting **<u>all</u>** of the following criteria:

   a. The patient has a DSM-V-TR diagnosis of opioid use disorder

-AND-

c. The prescriber attests that the patient is currently receiving substance abuse rehabilitation services as part of their therapy for opioid dependence.

-AND-

d. The prescriber has a 'X' waivered DEA license to prescribe buprenorphine products, as per the requirements of the Drug Addiction Treatment Act of 2000

-AND-

e. If buprenorphine sublingual tablet is to be administered, there is a documented intolerance to Naloxone, or the patient is pregnant/breast-feeding

-AND-

f. If the request is for a non-preferred product, the patient must have a reason or special circumstance that they cannot used the preferred product.

Authorization of therapy will be issued for an initial 3 months. Up to 24 mg per day of Suboxone, or equivalent dosing of an alternative medication, will be authorized for the initial period.

B. Reauthorization

1. **Suboxone Film, buprenorphine sublingual tablet, Zubsolv, Bunavail, or buprenorphine/naloxone tablet** will only be approved based on meeting **all** of the following criteria:

a. The patient has been prescribed a buprenorphine product for the purpose of opioid use disorder maintenance therapy

-AND-

b. There have been no fills of other opiate medications on the patient's medication history since the initiation of buprenorphine therapy, unless the prescriber has documented that the patient has relapsed

-AND-

c. The provider attests that the patient continues to receive urine drug screenings as part of their therapy for opioid dependence.

-AND-

d. The prescriber attests that the patient continues to receive substance abuse rehabilitation services as part of their therapy for opioid dependence.

-AND-

g. The prescriber has a 'X' waivered DEA license to prescribe buprenorphine products, as per the requirements of the Drug Addiction Treatment Act of 2000.

-AND-

g. If buprenorphine sublingual tablet is to be administered, there is a documented intolerance to Naloxone, or the patient is pregnant/breast-feeding

-AND-

h. If the request is for a non-preferred product, the patient must have a reason or special circumstance that they cannot used the preferred product.

Authorization of therapy will be issued for 12 months. Up to 16 mg per day of Suboxone, or equivalent dosing of an alternative medication, will be authorized for the reauthorization period.

3. References:

1. Suboxone® Film Prescribing Information. Reckitt Benckiser Pharmaceuticals, Inc; August 2012.
2. Subutex® Prescribing Information. Reckitt Benckiser Pharmaceuticals, Inc; Sept 2006.
3. American Psychiatric Association: Work Group on Substance Use Disorders. Practice Guidelines for the Treatment of Patients With Substance Use Disorders. APA Practice Guidelines 2005:1-276.
4. 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.
5. Lacy CF, Armstrong LL, Goldman MP, et al. Drug Information Handbook. A comprehensive resource for all clinicians and healthcare professionals 15th ed. Ohio: Lexi-Comp 2007.
6. Dunlop AJ, Panjari M, O'Sullivan H, Henschke P, Love A, Lintzeris N. Clinical guidelines for the use of buprenorphine in pregnancy. Fitzroy, Turning Point Alcohol and Drug Centre. Accessed August 2009 as: http://www.turningpoint.org.au/library/CTG_Bup_Pregnancy_060104.pdf.

7. Lindeman S, Nydert P, Svensson JO, et al. Transfer of Buprenorphine into breast milk and calculation of infanct drug dose. *J Hum Lact* 2009;25(2):198-205.
8. Orman JS, Keating GM. Buprenorphine/naloxone. A review of its use in the treatment of opioid dependence. Drugs 2009;69(5):577-607.
9. Drug Addiction Treatment Act of 2000 (DATA 2000). Accessed at http://buprenorphine.samhsa.gov/titlexxxv.html.
10. Wong S, Ordean A, Kahan M, et al. Substance Use in Pregnancy. *JOGC*. 2011; 256: 367-384.
11. Substance Abuse and Mental Health services Administration (SAMHSA). Accessed at https://www.samhsa.gov/disorders/substance-use.

Program	Program type – Prior Authorization
Change Control	
Date	Change
Sept 2009	Criteria were taken from the previously approved Unison policy, RX06 Suboxone. Prescriber certification requirement was added. Initial approval period extended to 6 months. Subutex criteria requires intolerance to naloxone or pregnancy. Policy was reformatted.
Dec 2010	Annual Review. Suboxone sublingual film added to product list.
March 2011	Changed requirement of the results of a urine drug screen for the Pennsylvania Plan under III.B.1.c. No urine drug screen results are required. Only a confirmation that the urine drug screen was completed is required.
December 2011	Changed initial authorization period to 3 months, and listed a 24 mg per day quantity limit within this initial authorization period. Reauthorization period remains the same, but added a 16 mg per day authorization limit for this period.
December 2012	Added the new 12/3 mg and 4/1 mg film strengths to the non-preferred drug table. These strengths have not yet been reviewed by P&T Committee.
June 2013	• Removed requirement of the results of a urine drug screen for the Pennsylvania Plan. • Added requirement for documentation required from the prescribing physician showing the patient is receiving substance abuse rehabilitation services. • Added requirement that the urine drug screen is submitted with the reauthorization prior authorization request • Added requirement that the urine drug screen is submitted with the reauthorization prior authorization request
August 2013	Added requirement that the urine drug screen is completed within the last 30 days
December 2015	Annual Review

July 2016	Changed reauth duration from 3 months to 6 months. Added Zubsolv to the policy. Changed AmeriChoice language to UnitedHealthcare.
October 2016	Added a grid with the preferred products. Added non-preferred criteria to the initial and reauthorization criteria.
December 2016	Added Bunavail and buprenorphine/naloxone tablet to policy
March 2017	Changed the reauthorization duration from 6 months to 12 months.
April 2017	Added “breast-feeding” as a reason patient cannot take naloxone. Changed the urine drug screen requirement and rehabilitation services requirement from documentation required to a provider attestation. Removed the requirement that buprenorphine cannot be used for pain management.