Utilization Management Policy Name: Medication Assisted Therapy (Buprenorphine) – Enhanced and Essential Formularies

Restricted Product(s):

- BUNAVAIL® (buprenorphine-naloxone buccal film)
- ZUBSOLV® (buprenorphine-naloxone hcl sl tab)

Unrestricted Product(s):

Quantity limits apply to all buprenorphine products

- buprenorphine hcl sl (Subutex®)
- buprenorphine-naloxone hcl sl tab (Suboxone®)
- Suboxone® (buprenorphine-naloxone hcl sl films)

FDA Approved Use:

- For the treatment of opioid dependence. Prescription use of this product is limited under the Drug Addiction Treatment Act.
  - Subutex is preferred for induction

Rationale:

Products such as buprenorphine-naloxone hcl sl tablets (Suboxone) and Suboxone Films treat the same condition at a substantially lower cost to members with equal results. Quantity limits have been added to ensure safe and effective use.

Criteria Summary:

Trial of effect and lower cost product; exception to quantity limitation

1. Patients requesting the use of Bunavail or Zubsolv have tried and failed or have a clinical contraindication/intolerance to generic buprenorphine hcl-naloxone hcl sl tab (Suboxone) or Suboxone Films ; **AND**
2. For formularies that exclude (non-formulary) the requested medication, Non-formulary Exception Criteria applies (outlined below)*

Duration of Approval: 365 days

Quantity Limitations: quantity limitations apply to brand and associated generic products.

Medication	Quantity per Day (unless specified)
BUNAVAIL® (buprenorphine-naloxone buccal film) 2.1mg/0.3mg	3 films

BUNAVAIL® (buprenorphine-naloxone buccal film) 4.2mg/0.7mg	2 films
BUNAVAIL® (buprenorphine-naloxone buccal film) 6.3mg/1mg	2 films
buprenorphine hcl sl (Subutex®) 2mg	3 tablets for 5 days; 15 tablets total
buprenorphine hcl sl (Subutex®) 8mg	3 tablets for 5 days; 15 tablets total
buprenorphine hcl-naloxone hcl sl tab (Suboxone®) 2mg/0.5mg	4 tablets
buprenorphine hcl-naloxone hcl sl tab (Suboxone®) 8mg/2mg	3 tablets
SUBOXONE (buprenorphine-naloxone hcl sl film) 2mg/0.5mg	4 films
SUBOXONE (buprenorphine-naloxone hcl sl film) 4mg/1mg	1 films
SUBOXONE (buprenorphine-naloxone hcl sl film) 8mg/2mg	2 films
SUBOXONE (buprenorphine-naloxone hcl sl film) 12mg/3mg	2 films
ZUBSOLV® (buprenorphine-naloxone hcl sl tab) 0.7mg/0.18mg	1 tablet
ZUBSOLV® (buprenorphine-naloxone hcl sl tab) 1.4mg/0.36mg	3 tablets
ZUBSOLV® (buprenorphine-naloxone hcl sl tab) 2.9mg/0.71mg	1 tablet
ZUBSOLV® (buprenorphine-naloxone hcl sl tab) 5.7mg/1.4mg	3 tablets
ZUBSOLV® (buprenorphine-naloxone hcl sl tab) 8.6mg/2.1mg	2 tablets
ZUBSOLV® (buprenorphine-naloxone hcl sl tab) 11.4mg/2.9mg	1 tablet

Quantity Limit Exception Criteria:

1. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90 day titration period); **AND**
2. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
3. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert; **OR**
4. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed); **OR**
5. If the request is for buprenorphine (Subutex) and over the induction quantity (15 tablets for 5 days);
    a. The patient has a medical record documentation of a clinical medication allergy (excludes medication intolerance) to naloxone or naltrexone and requires use of buprenorphine only **[medical record documentation required]; OR**
    b. The patient is pregnant or breastfeeding a child **[medical record documentation required]**; **AND**
6. For increased quantities, the quantity requested up to a maximum dose of the following may be approved:

a. 12.6 mg per day of buprenorphine as Bunavail,
b. 24 mg per day of buprenorphine as Suboxone, buprenorphine/naloxone tablets, or buprenorphine,
c. 17.2 mg per day of buprenorphine as Zubsolv.

Duration of Approval: 365 days

***Non-formulary Exception Criteria**

Non-Formulary Exception criteria applies on formularies which exclude requested product(s). Satisfactory completion of criteria points (above) may satisfy some, or all, portions of the Non-Formulary Exception Criteria. This criteria is summarized as:

a) Request must be for an FDA approved indication; **AND**
b) Patient must have a trial and failure of up to **TWO** formulary medications or a clinical contraindication/intolerance to those medications not tried.

References: all information referenced is from FDA package insert unless otherwise noted below.

Drug Addiction Treatment Act of 2000. http://buprenorphine.samhsa.gov/fulllaw.html. Accessed 12 Sept 2012
Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. Journal of Addiction Medicine. 2015;9(5):358-367. doi:10.1097/ADM.0000000000000166.

Policy Implementation/Update Information: originated: January 2013; last updated: November 2018

Nov 2018: Updated criteria to step through buprenorphine hcl-naloxone hcl sl tab (Suboxone) or Suboxone films
Nov 2018: Removed prior authorization for Suboxone sl films, buprenorphine-naloxone hcl sl tab, and buprenorphine hcl sl tablets; Added quantity limit criteria point for buprenorphine hcl sl tablets; updated maximum dosages on products.
Aug 2018: Removed requirement for abstinence from illicit/problematic substance use; updated to require abstinence from opioids at initiation of therapy; consultation on problematic benzodiazepine/ethanol use; consideration of therapy intensification for polysubstance and relapse; aligned psychosocial requirements to the minimum recommended by guidelines; added a reminder to providers to submit stabilization/maintained therapy request at the time of induction.
Jul 2018: Removed generic buprenorphine-naloxone hcl sl film due to market removal.
Jun 2018: Updated policy to include the new to market generic buprenorphine-naloxone hcl sl film
Apr 2018: Separate policy created for Net Results formulary
Dec 2017: Corrected typographical error. Buprenorphine (Subutex) 2mg tablet has a quantity limit of 3 daily and was posted as 4.

Sep 2017: Medical record requirements removed for Subutex
Jul 2017: Reformatted; updated FDA indication on Bunavail to include induction.
Jan 2017: Added new to market Zubsolv 0.7mg/0.18mg to policy.
Jan 2017: Reviewed for ASO Net Results and Essential formularies; non-formulary verbiage added.
Jul 2016: Removal of 15 tablets / 90 day quantity limit on Subutex induction therapy.
Jul 2016: Revised quantity limits for all medications covered in this policy.
Sep 2015: Added new strengths (2.9 mg/0.71 mg, 11.4 mg/2.9 mg) of Zubsolv to the criteria.
Jan 2013: Original utilization management criteria issued.

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- You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, Civil Rights Coordinator - Privacy, Ethics & Corporate Policy Office is available to help you.

- You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at *https://ocrportal.hhs.gov/ocr/portal/lobby.jsf,* or by mail or phone at: U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 **1-800-368-1019, 800-537-7697** (TDD). Complaint forms are available at *http://www.hhs.gov/ocr/office/file/index.html.*

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