| Market Applicability/Effective Date | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **LA** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | X |

*FHK- Florida Healthy Kids

# Subutex (buprenorphine)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization<br>Quantity Limit | Initial Requests: 3 months<br><br>Maintenance Therapy: Additional prior authorization required for each additional 12 months |

| Medications | Quantity Limit |
|---|---|
| Subutex (buprenorphine) 2mg sublingual tablet | 12 tablets per 90 days |
| Subutex (buprenorphine) 8mg sublingual tablet | 3 tablets per 90 days |

## APPROVAL CRITERIA

Initial request for 12 tablets per day of the 2 mg strength OR 3 tablets per day of the 8 mg strength for continuation of therapy after induction dose may be approved if the following criteria are met;

I. Individual is 16 years of age or older; **AND**
II. Subutex (buprenorphine HCl) is being used for opioid use disorder; **AND**
III. Prescribers personal DEA and unique DATA 2000 waiver identification number (that is, X DEA number) provided; **AND**
IV. Individual and prescriber have a formal written agreement regarding treatment for opioid use disorder (documentation not required, but verification upon request must be provided); **AND**
V. Individual must participate in a comprehensive rehabilitation program (consisting of either inpatient or outpatient services) that includes psychosocial support provided by a program counselor qualified by education, training, or experience to assess the psychological and sociological background of individuals receiving treatment (documentation of treatment not required, but verification upon request must be provided); **AND**
VI. One of the following:
    a. Individual is pregnant; **OR**
    b. Individual has a documented allergic reaction to Suboxone (hypersensitivity to naloxone component);

**AND**
VII. Individual will not utilize buprenorphine in combination with any of the following

| Market Applicability/Effective Date | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **LA** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | X |

*FHK- Florida Healthy Kids

medications without written documentation from the prescriber of buprenorphine regarding medical necessity and evidence that individual has been counseled on the risk of concomitant use:

a. Opioid agents; **OR**
b. Sedative/hypnotic agents (including non-benzodiazepine hypnotics and phenobarbital containing agents; **OR**
c. Benzodiazepine agents.

Maintenance requests for 12 tablets per day of the 2 mg strength OR 3 tablets per day of the 8 mg strength may be approved if the following criteria are met:

I. Individual is 16 years of age or older; **AND**
II. Subutex (buprenorphine HCl) is being used for opioid use disorder; **AND**
III. Prescribers personal DEA and unique DATA 2000 waiver identification number (that is, X DEA number) provided; **AND**
IV. Individual and prescriber have a formal written agreement regarding treatment for opioid use disorder (documentation not required, but verification upon request must be provided); **AND**
V. Prescriber must utilize the state prescription drug monitoring program (PDMP) where applicable by state regulation prior to issuing prescription to ensure individual is not concurrently utilizing opioids, benzodiazepines or sedative/hypnotic agents (documentation not required, but verification upon request must be provided); **AND**
VI. Individual must participate in clinically appropriate psychosocial support services (documentation of treatment plan not required, but verification upon request must be provided); **AND**
VII. Individual has undergone random clinical drug testing a minimum of eight times per year [42 CFR § 8.12(f) (6). *Drug abuse testing services*] with the following noted:
    a. Individual has a negative drug screen for opioids and other illicit substances (such as but not limited to cocaine and methamphetamine) and positive result for buprenorphine to continue current treatment plan (documentation of drug screen results not required, but verification upon request must be provided); **OR**
    b. If positive drug screen (for opioids or other illicit substances) or negative drug screen for buprenorphine, evidence that the treatment plan has been re-evaluated and amended to achieve treatment goals (documentation of drug screen results not required, but verification upon request must be provided;

**AND**

VIII. One of the following:
    a. Individual is pregnant; OR
    b. Individual has a documented allergic reaction to Suboxone (hypersensitivity to naloxone component)

**AND**



This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

| Market Applicability/Effective Date | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **LA** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | X |

*FHK- Florida Healthy Kids

IX. Individual will not utilize buprenorphine in combination with any of the following medications without written documentation from the prescriber of buprenorphine regarding medical necessity and evidence that individual has been counseled on the risk of concomitant use:

a. Opioid agents; **OR**
b. Sedative/hypnotic agents (including non-benzodiazepine hypnotics and phenobarbital containing agents); **OR**
c. Benzodiazepine agents.

******Note: Subutex (buprenorphine HCl) is NOT indicated for use to manage chronic pain******

| State Specific Mandates | | |
|---|---|---|
| State name | Date effective | Mandate details (including specific bill if applicable) |
| N/A | N/A | N/A |

**Key References**:


Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.