

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	NA

*FHK- Florida Healthy Kids

Buprenorphine/Naloxone Agents – All MCD except WA

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial PA Request: 3 months Maintenance Therapy: Additional prior authorization required for each additional 12 months Initial Quantity Limit Requests: 3 months Maintenance Therapy Quantity Limit Request – 1 year

Medications	Status	Strength	Quantity Limit
Bunavail (buprenorphine with naloxone)	Non-Preferred	2.1mg – 0.3mg 4.2mg – 0.7mg 6.3mg – 1mg	4 buccal films per day (maintenance dose limit, 8.4mg/1.4 mg per day) 2 buccal films per day (maintenance dose limit, 8.4mg/1.4 mg per day) 1 buccal film per day (maintenance dose limit, 8.4mg/1.4 mg per day) 12.6 mg/2.1 mg per day – initial 3 months therapy (for all strengths)
Buprenorphine with naloxone Sublingual Tablet	Preferred	8mg – 2mg 2mg – 0.5mg	2 tablets per day (maintenance dose limit, 16 mg buprenorphine per day) 8 tablets per day (maintenance dose limit, 16 mg buprenorphine per day) 24 mg per day –initial 3 months therapy (for all strengths)
Suboxone (buprenorphine with naloxone) Sublingual Film	Preferred; Non-Preferred	2mg – 0.5mg	8 films per day (maintenance dose limit, 16 mg buprenorphine per day)

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	NA

*FHK- Florida Healthy Kids

	for KY, WA**	4mg – 1mg 8mg – 2mg 12mg – 3 mg	4 films per day (maintenance dose limit, 16 mg buprenorphine per day) 2 films per day (maintenance dose limit, 16 mg buprenorphine per day) 1 film per day (maintenance dose limit, 16 mg buprenorphine per day) 24 mg per day – initial 3 months therapy (for all strengths)
Zubsolv (buprenorphine with naloxone)	Non-Preferred	2.9mg – 0.7mg 11.4mg – 2.9mg 1.4mg – 0.36mg 5.7mg – 1.4mg 8.6mg – 2.1 mg	3 tablets per day (maintenance dose limit, 11.4mg/2.9mg per day) 1 tablet per day (maintenance dose limit, 11.4mg/2.9mg per day) 8 tablets per day (maintenance dose limit, 11.4mg/2.9mg per day) 2 tablets per day (maintenance dose limit, 11.4mg/2.9mg per day) 1 tablet per day (maintenance dose limit, 11.4mg/2.9mg per day) 17.1 mg/4.2 mg per day – initial 3 months therapy (for all strengths)

****Please see State Specific Mandates for WA**

****New York Medicaid – please see state specific mandates below**

APPROVAL CRITERIA

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	NA

*FHK- Florida Healthy Kids

Initial requests for all non-preferred buprenorphine with naloxone products (Bunavail, and Zubsolv for all markets except WA and KY; for KY, Suboxone sublingual film is also non-preferred) may be approved for individuals who meet the following criteria:

- I. Individual meets one of the following (a or b):
 - a. Individual has been on the requested product in the previous 180 days **OR**
 - b. Individual has had a trial of one preferred buprenorphine with naloxone agent (current preferred agents: buprenorphine/naloxone sublingual tablets, Suboxone film for all markets except WA and KY; for KY, only buprenorphine/naloxone sublingual tablets are preferred) in the previous 180 days;

AND

- II. Individual is being treated for opioid use disorder; **AND**
- III. Individual is 16 years of age or older; **AND**
- IV. Prescribers personal DEA and unique Drug Addiction Treatment Act (DATA) 2000 waiver identification number (that is, X DEA number) provided; **AND**
- V. 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**
- VI. 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 plan not required, but verification upon request must be provided) (42 CFR § 8.12(f) (5) *Counseling services*); **AND**
- VII. Individual will not utilize buprenorphine with naloxone in combination with any of the following medications without written documentation from the prescriber of buprenorphine with naloxone regarding medical necessity and evidence that individual has been counseled on the risk of concomitant use:
 - a. Opioid agents (including tramadol); **OR**
 - b. Sedative/hypnotic agents (including non-benzodiazepine hypnotics and phenobarbital containing agents); **OR**
 - c. Benzodiazepine agents.

Initial requests for Buprenorphine with naloxone sublingual tablets or Suboxone Sublingual Film may be approved for individuals who meet the following criteria:

- I. Individual is being treated for opioid use disorder; **AND**
- II. Individual is 16 years of age or older; **AND**
- III. Prescribers personal DEA and unique Drug Addiction Treatment (DATA) 2000 waiver identification number (that is, X DEA number) provided; **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	NA

*FHK- Florida Healthy Kids

- 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 plan not required, but verification upon request must be provided) (42 CFR § 8.12(f) (5) *Counseling services*); **AND**
- VI. Individual will not utilize buprenorphine with naloxone in combination with any of the following medications without written documentation from the prescriber of buprenorphine with naloxone regarding medical necessity and evidence that individual has been counseled on the risk of concomitant use:
 - a. Opioid agents (including tramadol); **OR**
 - b. Sedative/hypnotic agents (including non-benzodiazepine hypnotics and phenobarbital containing agents); **OR**
 - c. Benzodiazepine agents.

Maintenance therapy requests for all dosage forms of buprenorphine with naloxone (Suboxone (buprenorphine with naloxone), Bunavail (buprenorphine with naloxone), Zubsolv (buprenorphine with naloxone) and buprenorphine with naloxone sublingual tablets) may be approved for individuals who meet the following criteria:

- I. Individual is being treated for opioid use disorder; **AND**
- II. Individual is 16 years of age or older; **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:

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	NA

*FHK- Florida Healthy Kids

- a. Individual has negative urine 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.** Individual will not utilize buprenorphine with naloxone in combination with any of the following medications without written documentation from the prescriber of buprenorphine with naloxone 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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
WA MCD	10/1/15	WA Medicaid has no PA requirement for buprenorphine/naloxone products; only specific quantity limit override criteria for buprenorphine daily doses above 24mg per day. WA MCD has specific criteria documents.
New York MCD	8/15/16	New York Medicaid – A10725 Part B: No prior authorization can be required for initial or renewal prescription of preferred/formulary buprenorphine/naloxone agents. 17 § 4. Section 364-j of the social services law is amended by adding a 18 new subdivision 26-b to read as follows: 19 <u>26-b. Managed care providers shall not</u> 20 <u>require prior authorization for</u> 21 <u>an initial or renewal prescription</u> <u>for buprenorphine or injectable</u> 22 <u>naltrexone for detoxification or</u> <u>maintenance treatment of opioid</u> 23 <u>addiction unless the prescription is for</u> <u>a non-preferred or non-formu-</u> 24 <u>lary form of the drug or as otherwise</u> <u>required by section 1927(k)(6) of</u> 25 <u>the Social Security Act.</u> 26 § 5. Section 273 of the public health law is amended by adding a new

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	NA

*FHK- Florida Healthy Kids

		<p>26 subdivision 10 to read as follows:</p> <p>27 <u>10. Prior authorization shall not be</u></p> <p>28 <u>required for an initial or</u></p> <p>29 <u>renewal prescription for buprenorphine</u></p> <p>30 <u>or injectable naltrexone for</u></p> <p>31 <u>detoxification or maintenance treatment of</u></p> <p><u>opioid addiction unless the</u></p> <p><u>prescription is for a non-preferred or</u></p> <p><u>non-formulary form of such drug</u></p> <p><u>as otherwise required by section</u></p> <p><u>1927(k)(6) of the Social Security Act.</u></p>
--	--	---

Key References:

CDC Grand Rounds: Prescription Drug Overdoses – U.S. Epidemic. Morbidity and Mortality Weekly Report 2012. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm>. Accessed 07-13-2014.

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: A Treatment Improvement Protocol TIP 40. U.S. Department of Health and Human Services. <http://store.samhsa.gov/shin/content//SMA05-4003/SMA05-4003.pdf>. Pub date 2004. Accessed June 26, 2015.

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>. Accessed: June 26, 2016.

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.

Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs: A Treatment Improvement Protocol. TIP 43. U.S. Department of Health and Human Services. <http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf>. Pub date 2005, Rev 2012. Accessed June 26, 2015.

Substance Abuse and Mental Health Services Administration. *Federal Guidelines for Opioid Treatment Programs*. HHS Publication No. (SMA) PEP15-FEDGUIDEOTP. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015. <http://store.samhsa.gov/shin/content//PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf>. Pub date 2015. Accessed July 14, 2015.

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.