

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	NA	NA	NA	NA	NA

Buprenorphine/Naloxone Agents

Override(s)	Approval Duration
Quantity Limit Step Therapy	1 year

Medications	Status	Strength	Quantity Limit
Buprenorphine with naloxone Sublingual Tablet	Preferred	2mg – 0.5mg	12 sublingual tablets per day*
		8mg – 2mg	3 sublingual tablets per day*
Buprenorphine with naloxone Sublingual Film (generic Suboxone file)	Preferred	2mg – 0.5mg	12 films per day*
		4mg – 1mg	6 films per day*
		8mg – 2mg	3 films per day*
		12mg – 3 mg	2 films per day*
Suboxone (buprenorphine with naloxone) Sublingual Film (Brand)	Non-Preferred	2mg – 0.5mg	12 films per day*
		4mg – 1mg	6 films per day*
		8mg – 2mg	3 films per day*
		12mg – 3 mg	2 films per day*

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			*Indicates FDA maximum recommended dose for specific drug and dosage strength – 24 mg/6 mg
Cassipa (buprenorphine with naloxone) Sublingual Film	Non-Preferred	16mg-4mg	1 film per day
Zubsolv (buprenorphine with naloxone) Sublingual Tablet	Non-Preferred	0.7mg-0.18mg	23 sublingual tablets per day
		1.4mg – 0.36mg	12 sublingual tablets per day
		2.9mg – 0.71mg	5 sublingual tablets per day
		5.7mg – 1.4mg	3 sublingual tablets per day
		8.6mg – 2.1 mg	2 sublingual tablets per day*
		11.4mg – 2.9mg	1 sublingual tablet per day
			*Indicates FDA maximum recommended dose for specific drug and dosage strength – 17.2 mg/4.2 mg
Bunavail (buprenorphine with naloxone) Buccal Films	Non-Preferred	2.1mg – 0.3mg	6 buccal films per day
		4.2mg – 0.7mg	3 buccal films per day*
		6.3mg – 1mg	2 buccal films per day
			*Indicates FDA maximum recommended dose for specific drug and dosage strength – 12.6 mg/2.1 mg

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.

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APPROVAL CRITERIA

Requests for all non-preferred buprenorphine with naloxone products (Bunavail, Cassipa film, Suboxone film (brand) and Zubsolv) for FL HK, GA, NV, and SC markets may be approved for individuals who meet the following criteria:

- I. Individual has had a trial of and inadequate response or intolerance to one preferred buprenorphine with naloxone agent (current preferred agents: buprenorphine/naloxone sublingual tablets, buprenorphine with naloxone sublingual film (generic Suboxone film);
OR
- II. If Cassipa is requested, individual has been stabilized and titrated to a dose of 16 mg buprenorphine using another marketed agent.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: November 29, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. 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://buprenorphine.samhsa.gov/Bup_Guidelines.pdf. Pub date 2004. Accessed July 6, 2018.
6. 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 July 6, 2018.
7. 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 6, 2018.
8. Cassipa [package insert]. North Wales, PA: Teva Pharmaceuticals USA, INC; 2018

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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