

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

# Sublocade (buprenorphine extended-release)

CG-DRUG-89

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Sublocade (buprenorphine extended-release) subcutaneous injection	May be subject to quantity limit

## APPROVAL CRITERIA

Sublocade (buprenorphine extended-release) subcutaneous injection may be approved when all of the following criteria have been met:

- A. The individual has been diagnosed with moderate to severe opioid dependence (opioid use disorder); **AND**
- B. The individual has initiated treatment with buprenorphine (8-24 mg per day) by sublingual tablet or its transmucosal equivalent, followed by dose adjustment for a minimum of 7 days to clinically optimize symptoms of cravings and withdrawal; **AND**
- C. The individual is clinically stable on buprenorphine by sublingual tablet or its transmucosal equivalent prior to initiation of injectable buprenorphine therapy; **AND**
- D. The individual is not concurrently receiving other maintenance or supplemental dosing with buprenorphine products; **AND**
- E. Injectable buprenorphine is being used as part of a comprehensive substance use disorder treatment program to include counseling and psychosocial support.

Sublocade (buprenorphine extended-release) subcutaneous injection may **not** be approved for all other indications, including but not limited to:

- A. When the above criteria have not been met; **OR**
- B. For individuals with contraindications to injectable buprenorphine, such as a pre-existing severe or moderate hepatic impairment or history of hypersensitivity to buprenorphine; **OR**
- C. For individuals not enrolled in a comprehensive substance use disorder treatment program.

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

**Key References:**

1. Buprenorphine. In: DrugPoints® Evaluations (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated December 5, 2017. Available at: <http://www.micromedexsolutions.com>. Accessed on March 22, 2018.
2. Gowing L, Ali R, White JM, Mbewe D. Buprenorphine for managing opioid withdrawal. Cochrane Database Syst Rev. 2017;(2):CD002025.
3. 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. 2015. Available at: [http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24#search="naltrexone"](http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24#search=). Accessed on March 22, 2018.
4. Sublocade [Product Information Label], Indivior Inc, North Chesterfield, VA. Updated November 30, 2017. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/209819s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209819s000lbl.pdf). Accessed on March 22, 2018.
5. Substance Abuse and Mental Health Services Administration (SAMHSA) Buprenorphine Waiver Management. Available at: <http://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management>. Accessed on March 22, 2018.

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