

## Commercial/Healthcare Exchange PA Criteria

*Effective: November 7<sup>th</sup>, 2018*

**Prior Authorization:** Lucemyra

**Products Affected:** Lucemyra (lofexidine)

**Medication Description:**

Lofexidine is a central alpha-2 adrenergic receptor agonist that binds to adrenergic receptors, reducing the release of norepinephrine and decreasing sympathetic tone. Lofexidine is the first FDA-approved non-opioid agent indicated to minimize withdrawal symptoms to aid in sudden opioid discontinuation. According to the American Society of Addiction Medicine (ASAM), buprenorphine and methadone are the standard treatment options to manage withdrawal symptoms from opioids. Other options in the ASAM guidelines to manage opioid withdrawal are alpha-2 adrenergic agonists, such as clonidine and lofexidine. Due to its high selectivity for the alpha-2A receptor, lofexidine is thought to be associated with less anti-hypertensive activity than clonidine, and therefore might be more useful in an outpatient setting where blood pressure monitoring is more difficult.

**Covered Uses:** To minimize withdrawal symptoms to aid in sudden opioid discontinuation.

**Exclusion Criteria:**

- A. Patient is under 18 years of age
- B. Pregnancy or breast feeding
- C. Prolonged QT interval (> 450 msec for males, > 470 msec for females)

**Required Medical Information:**

- D. Diagnosis

**Age Restrictions:** ≥ 18 years of age

**Prescriber Restrictions:** N/A

**Coverage Duration:** 6 months

**Other Criteria:**

- A. Prescriber to provide verbal attestation that if patient is currently taking methadone, baseline electrocardiogram (ECG) has been performed; AND
- B. Prescriber to provide verbal attestation that patient is NOT prescribed concurrent opioid medication without explanation (verified by state opioid database, if available)

**References:**

1. Lucemyra [package insert]. Louisville, KY; US WorldMeds; May 2018.
2. Weiss RD
3. Gorodetzky CW, Walsh SL, Martin PR, et al. A phase III, randomized, multi-center, double blind, placebo controlled study of safety and efficacy of lofexidine for relief of symptoms in individuals undergoing inpatient opioid withdrawal. Drug Alcohol Depend. 2017; 176: 79-88. DOI: 10.1016/j.drugalcdep.2017.02.020
4. Gowing L, Farrell MF, Ali R, et al. Alpha2-adrenergic agonists for the management of opioid withdrawal. Cochrane Database Syst Rev. 2016 May 3;(5):CD002024. DOI: 10.1002/14651858.CD002024.pub5.
5. 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. J Addict Med. 2015 Sep-Oct;9(5):358-67. DOI: 10.1097/ADM.000000000000166. Available at: <https://www.asam.org/resources/guidelines-and-consensus-documents/npg>. Accessed August 15, 2018
6. Nicholls L, Bragaw L, Ruetsch C. Opioid dependence treatment and guidelines. J Manag Care Pharm. 2010 Feb;16(1 Suppl B):S14-21. Available at <http://www.amcp.org/data/jmcp/S14-S21.pdf>. Accessed August 15, 2018

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	11/7/2018