# Lucemyra (lofexidine)

## NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

## BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

## DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Lucemyra is indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

## POLICY

Criteria for Initial Approval

Additional quantities of the requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for mitigation of opioid withdrawal symptoms in a patient undergoing abrupt discontinuation of an opioid
  **AND**
- The patient requires additional quantities due to multiple attempts of opioid discontinuation within a three month time period

Quantity Limits Apply

| Initial Quantity Limit | Post Limit Quantity Limit |
|---|---|
| 224 tablets/90 days | 448 tablets/90 days |

## RATIONALE

The usual Lucemyra starting dosage is three 0.18 mg tablets taken orally 4 times daily during the period of peak withdrawal symptoms (generally the first 5 to 7 days following last use of opioid) with dosing guided by symptoms and side effects. There should be 5 to 6 hours between each dose. The total daily dosage of Lucemyra should not exceed 2.88 mg (16 tablets) and no single dose should exceed 0.72 mg (4 tablets).[1-3] Initial quantity limits will be set to allow for the maximum dose of 16 tablets per day. If the patient is requesting more than the initial daily dose quantity limit, then the claim will reject.

Lucemyra treatment may be continued for up to 14 days with dosing guided by symptoms.[1-4] If the patient is requesting more than a 14-day supply within the past 90 days, then the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Lucemyra is indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.[1-3] According to the American Society of Addiction Medicine (ASAM) National Practice Guideline for the Treatment of Opioid Use Disorder, alpha-2 adrenergic agonists (e.g., FDA-approved lofexidine and off-label clonidine) are safe and effective for management of opioid withdrawal.[4]

Additional quantities of Lucemyra beyond a 14-day supply per three month period will be approved when the patient requires additional quantities due to multiple attempts of opioid discontinuation within that time period. The post limit will allow 16 tablets per day for a duration of 28 days (i.e., a second 14-day course of treatment) in a 3-month period.

## PROCEDURES AND BILLING CODES

**To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.**

## REFERENCES


- Lucemyra [package insert]. Louisville, KY: US WorldMeds, LLC; November 2019.
- Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed November 2020.
- Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed November 2020.
- American Society of Addiction Medicine National Practice Guideline for the Treatment of Opioid Use Disorder. https://www.asam.org/docs/default-source/quality-science/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2. Accessed November 2020.


## POLICY HISTORY

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