Lucemyra (lofexidine)

**Background**
Lucemyra (lofexidine) is a central alpha-2 adrenergic agonist that binds to receptors on adrenergic neurons. This reduces the release of norepinephrine and decreases sympathetic tone. Central alpha-2 agonists are particularly beneficial for treating opiate withdrawal symptoms related to autonomic hyperactivity such as tachycardia, increased blood pressure, anxiety, nausea, vomiting, chills, and sweating (1).

**Regulatory Status**
FDA-approved indication: Lucemyra is a central alpha-2 adrenergic agonist indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults (1).

There is a risk of hypotension, bradycardia, and syncope with Lucemyra therapy. Vital signs should be monitored and patients should be advised on how to minimize the risk of these cardiovascular effects and manage symptoms, should they occur. Lucemyra use should be avoided in patients with severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, or chronic renal failure, as well as in patients with marked bradycardia (1).

Lucemyra prolongs the QT interval. Lucemyra should be avoided in patients with congenital long QT syndrome. ECG monitoring is recommended in patients with electrolyte abnormalities, congestive heart failure, bradyarrhythmias, hepatic or renal impairment, or in patients taking other medicinal products that lead to QT prolongation (1).
Lucemyra potentiates the CNS depressant effects of benzodiazepines and may potentiate the CNS depressant effects of alcohol, barbiturates, and other sedating drugs such as opioids (1).

Patients who complete opioid discontinuation are at an increased risk of fatal overdose should they resume opioid use. Lucemyra should be used in conjunction with a comprehensive management program for treatment of opioid use disorder and patients and caregivers should be informed of increased risk of overdose (1).

Patients should be instructed not to discontinue Lucemyra therapy without consulting their healthcare provider, and therapy should be discontinued by reducing the dose gradually over 2 to 4 days (1).

The safety and effectiveness of Lucemyra in pediatric patients have not been established (1).

**Related policies**
Suboxone Drug Class

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Lucemyra may be considered medically necessary in patients 18 years of age and older with opioid withdrawal and if the conditions indicated below are met.

Lucemyra is considered investigational in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

18 years of age and older

**Diagnosis**

The patient must have the following:

Opioid withdrawal

**AND ALL** of the following:
1. Patient will NOT be receiving opioids
   a. Patient has had or will have abrupt discontinuation of opioids
2. Patient will receive counseling and psychosocial support

Prior – Approval Renewal Requirements
None

Policy Guidelines

Pre - PA Allowance
Quantity 168 tablets for 14 days

*Patient is allowed 1 Pre-PA and 1 PA approval per lifetime

Prior - Approval Limits

Quantity 228 tablets for 14 days

* Patient is allowed 1 Pre-PA and 1 PA approval per lifetime

Prior – Approval Renewal Limits
None

Rationale

Summary
Lucemyra (lofexidine) is a central alpha-2 adrenergic agonist that binds to receptors on adrenergic neurons. This reduces the release of norepinephrine and decreases sympathetic tone. Central alpha-2 agonists are particularly beneficial for treating opiate withdrawal symptoms related to autonomic hyperactivity such as tachycardia, increased blood pressure, anxiety, nausea, vomiting, chills, and sweating. The safety and effectiveness of Lucemyra in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Lucemyra while maintaining optimal therapeutic outcomes.

References
**5.60.30**

**Section:** Prescription Drugs

**Effective Date:** January 1, 2020

**Subsection:** Central Nervous System Drugs

**Original Policy Date:** October 1, 2018

**Subject:** Lucemyra

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**Policy History**

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**Keywords**

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.