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5.60.030

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	October 1, 2018
Subject:	Lucemyra	**Page:**	1 of 4

Last Review Date: June 13, 2024

Lucemyra

Description

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, bradyarrythmias, 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** if the conditions indicated below are met.

Lucemyra may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

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

1. Lucemyra [package insert]. Louisville, KY: US WorldMeds, LLC; September 2020.

Policy History

Date	Action
October 2018	Addition to PA
	Addition of Lucemyra to buprenorphine methadone lookback
November 2018	Annual review
	Reduced Pre-PA limit from 228 tablets for 14 days to 168 tablets for 14 days
December 2019	Annual review
December 2020	Annual review
June 2021	Annual review and reference update
June 2022	Annual review
June 2023	Annual review. Changed policy number to 5.60.030
December 2023	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.