

Lucemyra Prior Authorization with Quantity Limit Program Summary

This program applies to Blue Partner, Commercial, GenPlus, NetResults A series, SourceRx, and Health Insurance Marketplace.

OBJECTIVE

The intent of the Lucemyra Prior Authorization with Quantity Limit is to appropriately select patients according to product labeling and/or clinical guidelines, and to direct use to more cost-effective clonidine.

TARGET AGENT(S)

Lucemyra™ (lofexidine)

PRIOR AUTHORIZATION WITH QUANTITY LIMIT TARGETS

Brand (Generic)	GPI	Multi-Source Code	Quantity Limit
Lucemyra	62805045100315	M, N, O, Y	228 tablets (2 x 96
(lofexidine)			count bottles and 1 x
			36 count bottle) / 6
			months

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target Agent(s) will be approved when ALL of the following are met:

1. The requested agent will be used to mitigate opioid withdrawal symptoms to facilitate abrupt opioid discontinuation

AND

- 2. ONE of the following:
 - a. The patient has tried and had an inadequate response to therapy with oral clonidine or clonidine patch for the treatment of opioid withdrawal OR
 - b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to oral clonidine and clonidine patch that is not expected to occur with the requested agent

AND

- The patient does NOT have any FDA labeled contraindications to the requested agent AND
- 4. ONE of the following:
 - The patient's medication history (in the past 6 months) does NOT includes previous use of the requested agent AND the quantity (dose) requested is less than or equal to the program quantity limit
 - b. The patient's medication history (in the past 6 months) includes previous use of the requested agent AND BOTH of the following:
 - i. The prescriber has provided documentation in support of another course of therapy with the requested agent

AND

ii. The quantity (dose) requested is within the maximum FDA labeled dose and duration

Length of approval: 6 months

FDA Indications and Dosing¹

DA Indications and Dosing				
Medication	Indications	Dose and Interval		
Lucemyra™	Mitigation of opioid	The usual dosage is three 0.18 mg		
(lofexidine)	withdrawal symptoms to	tablets taken orally 4 times daily at 5-		
	facilitate abrupt opioid	to 6-hour intervals.		
Tablet	discontinuation in adults.			
(36 and 96		The total daily dose should not exceed		
count bottles)		16 tablets.		
		Treatment may be continued for up to		
		14 days with dosing guided by symptoms.		
		Symptoms.		
		Discontinue with a gradual dose		
		reduction over 2 to 4 days.		
		Hepatic or Renal Impairment: Dosage		
		adjustments are recommended based		
		on degree of impairment (1-3 tablets 4		
		times daily)		
		Lucensum should be stared and		
		Lucemyra should be stored and		
		dispensed in original container		

Efficacy

Lofexidine is a central alpha-2 adrenergic. The efficacy of lofexidine was studied in a phase III, randomized, double blind, placebo-controlled study including 264 patients. Patients were included if the patient was seeking treatment for opioid dependence (DSM-IV), met Structured Clinical Interview Axis I (SCID) criteria for dependence on a short-acting opioid, self-reported opioid use ≥ 21 of the last 30 days, showed signs of withdrawal just before randomization (score of ≥ 2 on the Handelsman Objective Opiate Withdrawal Scale [OOWS-Handelsman]), had a urine screen positive for opioids but negative for methadone or buprenorphine, provided written informed consent and completed the Addiction Severity Index (ASI) during screening and all other assessments (Short Opiate Withdrawal Scale [SOWS-Gossop], OOWS-Handelsman, and Modified Clinical Global Impression [MCGI]) during the baseline period.

Alpha-2 adrenergic agonists, including clonidine and lofexidine, lessen many symptoms of opioid withdrawal. Alpha-2 adrenergic agonists effectively relieve withdrawal symptoms of sweating, diarrhea, intestinal cramps, nausea, anxiety, and irritability. Alpha-2 adrenergic agonists are least effective for myalgias, restlessness, insomnia, and craving. Compared with reducing doses of methadone, these agents have been found to be comparably efficacious but more likely to cause side effects. Patients typically prefer opioid agonists for the management of withdrawal over alpha-2 adrenergic agonists. In many clinical settings, alpha-2 adrenergic agonists are used as adjuncts buprenorphine or methadone for opioid withdrawal. They are used first-line in supervised withdrawal in prisons and other environments that prohibit the use of opioid agonists and other controlled substances. Direct comparison of lofexidine and clonidine has not been definitive, but available research suggests equal efficacy between the two drugs with a trend towards less hypotension with lofexidine.³

Safety

Lofexidine has no black box warnings or contraindications.¹

REFERENCES

- 1. Lucemyra prescribing information. US WorldMeds, LLC. May 2018.
- 2. Gorodetzky CW, Walsh SL, 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 and Alcohol Dependence. 176 (2017) 79-88.
- 3. Medically supervised opioid withdrawal during treatment for addiction. UptoDate. Current through 6/2018. Last updated 6/12/18.

This pharmacy policy is not an authorization, certification, explanation of benefits or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All pharmacy policies are based on (i) information in FDA approved package inserts (and black box warning, alerts, or other information disseminated by the FDA as applicable); (ii) research of current medical and pharmacy literature; and/or (iii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

The purpose of pharmacy policies are to provide a guide to coverage. Pharmacy policies are not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.

