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 (lofexidine)	62805045100315	M, N, O, Y	228 tablets (2 x 96 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
3. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
4. ONE of the following:
   a. 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
      OR
   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 Dosing[1]

Medication	Indications	Dose and Interval
Lucemyra™ (lofexidine) Tablet (36 and 96 count bottles)	Mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.	The usual dosage is three 0.18 mg tablets taken orally 4 times daily at 5- to 6-hour intervals. The total daily dose should not exceed 16 tablets. Treatment may be continued for up to 14 days with dosing guided by 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) 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.[2]

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.