ALASKA MEDICAID Prior Authorization Criteria

LucemyraTM (lofexidine)

FDA INDICATIONS AND USAGE¹

LucemyraTM is a central alpha-2 receptor adrenergic agonist indicated for the mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

APPROVAL CRITERIA^{1,2,3}

- 1. Patient is 18 years of age or older AND;
- 2. Patient has a confirmed diagnosis of opioid dependence or opioid use disorder AND;
- 3. Prescribe by or in consultation with a pain management or addiction specialist AND;
- 4. Patient is undergoing or is scheduled to undergo abrupt opioid discontinuation **AND**;
- 5. Patient has a normal QT interval AND;
- 6. Patient has one of the following:
 - a. Tried and failed clonidine with in the last 6 months
 - b. Has a contraindication to clonidine
 - c. Has had a clinically significant adverse effect from clonidine use
 - d. LucemyraTM has been initiated in the emergency department

DENIAL CRITERIA^{1,2,3}

- 1. Patient is less than 18 years of age **OR**;
- 2. Patient does not have a confirmed diagnosis of opioid dependence or opioid use disorder **OR**;
- 3. LucemyraTM is not being prescribed by or in consultation with a pain management or addiction specialist **OR**;
- 4. Patient is not undergoing or is not scheduled to undergo abrupt opioid discontinuation **OR**;
- 5. Patient has an abnormal QT interval **OR**;
- 6. Patient does not have one of the following:
 - a. Tried and failed clonidine with in the last 6 months
 - b. Has a contraindication to clonidine
 - c. Has had a clinically significant adverse effect from clonidine use
 - d. LucemyraTM has been initiated in the emergency department

CAUTIONS¹

- There is a risk of hypotension, bradycardia and syncope associated with use.
- Patients with prolonged QT intervals should not use LucemryaTM.
- Concomitant use of CNS depressant drugs can increase the risk of CNS depression.

LucemryaTM Criteria Version: 1

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- Dose adjustments may be needed for patients with hepatic or renal impairment.
- Gradual dose reductions over 2 to 4 days is recommended for discontinuation.

DURATION OF APPROVAL

- Initial Approval: 7 days (112 tablets)
- Re-approval: 7 days (112 tablets) with documentation of positive patient response
- Note 3-7 days is often sufficient for treatment.

OUANTITY LIMITS

- 112 tablets per 7 days
- Max of 14 days per month
- Maximum of 3 14 day treatments per year

REFERENCES / FOOTNOTES:

- 1. LucemryaTM [Package Insert] Louisville, KY: US WorldMeds; 2018. Available at: https://hcp.lucemyra.com/LUCEMYRA-PI.pdf. Accessed on: December 10, 2018.
- 2. Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) National PracticeGuideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. J Addict Med. 2015 Sep-Oct;9(5):358-67.
- 3. Gowing L, Farrell M, Ali R, White JM. Alpha2-adrenergic agonists for the management of opioid withdrawal. Cochrane Database of Systematic Reviews 2016, Issue 5. Art. No.: CD002024.DOI: 10.1002/14651858.CD002024.pub5.

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