



## AETNA BETTER HEALTH®

### Prior Authorization guideline for Lucemyra (Lofexidine hcl)

#### Lucemyra is approved when the following are met:

- A. Member is 18 years of age or older
- B. Member has symptoms of opioid withdrawal due to abrupt opioid discontinuation
- C. Trial and failure, or contraindication to clonidine or member has a clinically significant adverse effect
- D. Attestation that member does not have congenital long QT syndrome, and provider has monitored member vital signs prior to dosing
- E. Attestation that member is being monitored for symptoms of orthostasis and bradycardia if taking a concurrent strong CYP2D6 inhibitor such as paroxetine, fluoxetine, bupropion, quinidine, or cinacalcet
- F. Attestation that member does not have severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure, or marked bradycardia

#### Initial Approval:

- 14 days per episode of treatment (224 total tablets)
- Dosing: Three 0.18 mg tablets taken orally four times daily for 7 days  
*Dosing adjusted based on tolerability and withdrawal symptoms and may continue for up to 14 days if needed*
- Quantity Limit: Maximum dose 0.72 mg/dose (4 tablets) or 2.88 mg/day (16 tablets per day) or 224 tablets

#### References:

1. British Psychological Society. Drug misuse: opioid detoxification: the NICE Guideline. Published 2008. <https://www.nice.org.uk/guidance/cg52/evidence/drug-misuse-opioid-detoxification-full-guideline-196515037> . Accessed August 21, 2018.
2. Pub Chem. Lofexidine Compound Summary, 2018. <https://pubchem.ncbi.nlm.nih.gov/compound/Lofexidine#section=Top> , Accessed August 30, 2018.

3. Felberbaum, M, FDA approves the first non-opioid treatment for management of opioid withdrawal symptoms in adults, May 16, 2016, <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm607884.htm> , Accessed August 24, 2018.
4. Lofexidine. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier. C2018- [cited 2018 August 22]. Available from: <http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=5048&sec=monindi&t=0>
5. Lofexidine [package insert]. US WorldMeds, LLC, 4441 Springdale Road, Louisville, KY, May 2018 [https://www.multivu.com/players/English/8314851-us-world-meds-lucemyra-fda-approval/docs/PrescribingInformat\\_1526505076265-1171755477.pdf](https://www.multivu.com/players/English/8314851-us-world-meds-lucemyra-fda-approval/docs/PrescribingInformat_1526505076265-1171755477.pdf) . Accessed August 22, 2018.
6. K Sevarino, A J Saxon, R Hermann, Waltham, MA. Medically supervised opioid withdrawal during treatment for addiction, Jun 12, 2018, [https://www.uptodate.com/contents/medically-supervised-opioid-withdrawal-during-treatment-for-addiction?search=opioid%20withdrawal%20treatment&sectionRank=1&usage\\_type=default&anchor=H2006857508&source=machineLearning&selectedTitle=1~150&display\\_rank=1#H2006857508](https://www.uptodate.com/contents/medically-supervised-opioid-withdrawal-during-treatment-for-addiction?search=opioid%20withdrawal%20treatment&sectionRank=1&usage_type=default&anchor=H2006857508&source=machineLearning&selectedTitle=1~150&display_rank=1#H2006857508) . Accessed August 23, 2018.