LOFEXIDINE

Generic	Brand	HICL	GCN	Exception/Other
LOFEXIDINE	LUCEMYRA	07803		

GUIDELINES FOR USE

1. Is the requested medication being used to mitigate opioid withdrawal symptoms to facilitate abrupt opioid discontinuation and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in a setting with close patient monitoring for a duration of Lucemyra (lofexidine) treatment not to exceed 18 days
   - Treatment with Lucemyra is being administered as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (e.g., stool softeners, sleep aids) and psychosocial support is in place to help prevent relapse

   If yes, **approve for 1 fill with a quantity limit of #264 tablets per 18 days.**
   If no, do not approve.
   DENIAL TEXT: The guideline name **LOFEXIDINE (Lucemyra)** requires that the requested medication is used to mitigate opioid withdrawal symptoms to facilitate abrupt opioid discontinuation. In addition, the following criteria must be met:
   - The patient is 18 years of age or older
   - The patient is in a setting with close patient monitoring for a duration of Lucemyra (lofexidine) treatment not to exceed 18 days
   - Treatment with Lucemyra is being administered as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (e.g., stool softeners, sleep aids) and psychosocial support is in place to help prevent relapse

RATIONALE
To ensure appropriate use of Lucemyra (lofexidine) consistent with FDA approved indications.

FDA APPROVED INDICATION
Lucemyra is indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

DOSAGE AND ADMINISTRATION
The usual Lucemyra starting dosage is three 0.18 mg tablets taken orally 4 times daily during the period of peak withdrawal symptoms (generally the first 5 to 7 days following last use of opioid) with dosing guided by symptoms and side effects. There should be 5 to 6 hours between each dose. The total daily dosage of Lucemyra should not exceed 2.88 mg (16 tablets) and no single dose should exceed 0.72 mg (4 tablets).

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FDA APPROVED INDICATION (CONTINUED)

DOSAGE AND ADMINISTRATION
Lucemyra treatment may be continued for up to 14 days with dosing guided by symptoms. Discontinue Lucemyra with a gradual dose reduction over a 2- to 4-day period to mitigate Lucemyra withdrawal symptoms (e.g., reducing by 1 tablet per dose every 1 to 2 days).The Lucemyra dose should be reduced, held, or discontinued for individuals who demonstrate a greater sensitivity to Lucemyra side effects. Lower doses may be appropriate as opioid withdrawal symptoms wane.

REFERENCES

- Lucemyra [Prescribing Information]. Louisville, KY. US Worldmeds, LLC. May 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/18
Created: 08/18
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P&T Approval: 07/18