BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 8/02/18**
SECTION: DRUGS	**LAST REVIEW DATE: 8/02/18**
	LAST CRITERIA REVISION DATE:
	ARCHIVE DATE:

LUCEMYRA™ (lofexidine hydrochloride) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Lucemyra (lofexidine) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a specialist in Addiction Medicine
2. Individual is 18 years of age or older
3. A confirmed diagnosis of **opioid abuse disorder to be used for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation**
4. Individual is physically dependent on short acting opioid (e.g., heroin, hydrocodone, oxycodone)
5. Used in conjunction with a comprehensive management program for treatment of opioid use disorder
6. Individual has failure, contraindication or intolerance to **ALL** the following preferred step therapy agents:
   - Methadone
   - Buprenorphine
   - Clonidine
7. Will not be used in patients with:
   - Severe coronary insufficiency
   - Recent myocardial infarction
   - Cerebrovascular disease, or chronic renal failure
   - Patients with marked bradycardia
   - Congenital long QT syndrome

Initial approval duration:
14 days per treatment, maximum number of tablets of 224
No refills, each request for re-treatment to be evaluated as an initial request

Description:

Lucemyra (lofexidine) is a central alpha-2 adrenergic agonist that binds to alpha-2A and alpha-2C receptors to reduce the release of norepinephrine and decrease sympathetic tone.

Efficacy of Lucemyra was evaluated by use of Short Opiate Withdrawal Scale of Gossop (SOWS-Gossop) score. Scores were compared to patients given placebo. SOWS-Gossop is a patient-reported outcome (PRO) instrument that evaluates opioid withdrawal symptoms of: feeling sick, stomach cramps, muscle spasms/twitching, feeling of cold, heart pounding, muscular tension, aches and pains, yawning, runny eyes and insomnia/problems sleeping. For each opioid withdrawal symptom, patients rate their symptom severity using four response options (none,

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mild, moderate, and severe). The SOWS-Gossop total score ranges from 0-30 where a higher score indicates a greater withdrawal symptom severity.

Symptoms assessed using the SOWS-Gossop are recorded as absent or mild for almost all patients given Lucemyra and more patients given Lucemyra complete opioid withdrawal treatment.

There are two main strategies for the management of opioid withdrawal. The first involves providing a gradual tapering dose of an opioid agonists, using either methadone or buprenorphine. The other is the use of alpha- 2 adrenergic agonist with other non-narcotic medications to help reduce withdrawal symptoms.

Opioid withdrawal results from over-activity of the noradrenergic system. Use of alpha-2 adrenergic agonists (clonidine, lofexidine) have a long history of use for the treatment of opioid withdrawal. Either of these agents are effective in alleviating some of the symptoms of opioid withdrawal.

Clonidine can be used at doses of 0.1–0.3 mg every 6–8 hours, with a maximum dose of 1.2 mg daily. It is often combined with other non-narcotic medications targeting other opioid withdrawal related symptoms such as use of a benzodiazepines for anxiety, loperamide or bismuth-salycilate for diarrhea, acetaminophen or nonsteroidal anti-inflammatory medications (NSAIDs) for pain, various medications for insomnia, and ondansetron for nausea.

The 2015 American Society of Addiction Medicine (ASAM) National Practice Guideline for Use of Medications in the Treatment of Addiction Involving Opioid Use recommends, based on consensus opinion, the inclusion of clonidine as a practice to support opioid withdrawal. While clonidine is not US FDA-approved for the treatment of opioid withdrawal, it has been extensively used off-label for this purpose.

The 2018 Medications for opioid use disorder for healthcare professionals, policy makers, patients & families. HHS Publication No. (SMA) 18-5063PT3. U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration Center for Substance Abuse treatment also recommends clonidine when opioid agonist medications are unavailable or not possible, to relieve withdrawal symptoms.

Definitions:

Clinical Opioid Withdrawal Scale (COWS)

Patient's name:_____	**Date and time:**___/___/___:_____
Reason for this assessment:_____	
Resting pulse rate:_____beats/minute Measured after patient is sitting or lying for one minute	**GI upset:** Over last half-hour
0 pulse rate 80 or below 1 pulse rate 81 to 100 2 pulse rate 101 to 120 4 pulse rate greater than 120	0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting

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Sweating: Over past half-hour not accounted for by room temperature or patient activity	**Tremor:** Observation of outstretched hands
0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face	0 no tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching
Restlessness: Observation during assessment	**Yawning:** Observation during assessment
0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 unable to sit still l for more than a few seconds	0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute
Pupil size	**Anxiety or irritability**
0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible	0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable or anxious 4 patient so irritable or anxious that participation in the assessment is difficult
Bone or joint aches: If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored	**Gooseflesh skin**
0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	0 skin is smooth 3 piloerrection of skin can be felt or hairs standing up on arms 5 prominent piloerrection
Runny nose or tearing: Not accounted for by cold symptoms or allergies	**Total score:**_____ The total score is the sum of all 11 items
0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks	Initials of person completing assessment:_____

Score: 5 to 12 = mild; 13 to 24 = moderate; 25 to 36 = moderately severe; more than 36 = severe withdrawal.
Wesson DR, Ling W. The Clinical Opiate Withdrawal Scale (COWS). J Psychoactive Drugs 2003; 35:253.

Resources:

Lucemyra product information accessed 07-12-18 at DailyMed:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bdcfe803-b556-47db-a54f-ae0f0e5be016

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Kampman K, Jarvis M, Comer S, et al.: American Society of Addiction Medicine (ASAM) National Practice Guideline for Use of Medications in the Treatment of Addiction Involving Opioid Use. J Addict Med 2015; 9(5):358-367

Substance Abuse and Mental Health Services Administration (SAMHSA) – 2018 Medications for opioid use disorder for healthcare professionals, policy makers, patients & families. HHS Publication No. (SMA) 18-5063PT3. U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration Center for Substance Abuse treatment

UpToDate: Medically supervised opioid withdrawal during treatment for addiction. Current through Jun 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/medically-supervised-opioid-withdrawal-during-treatment-for-addiction?search=opioid%20withdrawal&source=search_result&selectedTitle=3~149&usage_type=default&display_rank=3

UpToDate: Opioid withdrawal in the emergency setting. Current through Jun 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/opioid-withdrawal-in-the-emergency-setting?search=opioid%20withdrawal&source=search_result&selectedTitle=1~149&usage_type=default&display_rank=1

UpToDate: Opioid withdrawal: Clinical manifestations, course, assessment, and diagnosis. Current through Jun 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/opioid-withdrawal-clinical-manifestations-course-assessment-and-diagnosis?search=opioid%20withdrawal&source=search_result&selectedTitle=2~149&usage_type=default&display_rank=2

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.