Clinical Policy Title:	lorazepam
Policy Number:	RxA.710
Drug(s) Applied:	Loreev XR®
Original Policy Date:	12/07/2021
Last Review Date:	12/07/2021
Line of Business Policy Applies to:	All lines of business

Background

Lorazepam (Loreev XR®) is a benzodiazepine indicated for the treatment of anxiety disorders in adults who are receiving stable, evenly divided, three times daily dosing with lorazepam tablets.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
lorazepam (Loreev XR®)	Anxiety	Recommended dosage of Loreev XR® is equal to the total daily dose of lorazepam tablets (at the previous three times daily dosage), orally once daily in the morning. For dosage adjustments, discontinue Loreev XR® and switch to lorazepam tablets to adjust dosage.	10 mg/day orally

Hepatic Impairment: As with all benzodiazepines, the use of lorazepam, including Loreev XR®, may worsen hepatic encephalopathy. Therefore, Loreev XR® should be used with caution in patients with severe hepatic insufficiency and/or encephalopathy.

Dosage Forms

- Extended-release capsules: 1 mg, 2 mg, and 3 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Anxiety (must meet all):

1. Diagnosis of Anxiety disorders;

2. Age ≥ 18 years;
3. Member has been stable on lorazepam three times daily regimen prior to starting Loreev XR® therapy;
4. Dose does not exceed 10 mg/day.

Approval Duration
Commercial: 4 Months
Medicaid: 4 Months

II. Continued Therapy Approval

A. Anxiety (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Dose does not exceed 10 mg/day.

Approval Duration
Commercial: 4 months
Medicaid: 4 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
None

APPENDIX B: Therapeutic Alternatives
None

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity to benzodiazepines or any ingredients in Loreev XR®;
  - Acute narrow-angle glaucoma.

- Boxed Warning(s):
  - Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.
  - The use of benzodiazepines, including Loreev XR®, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Before prescribing Loreev XR® and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.
  - Abrupt discontinuation or rapid dosage reduction of Loreev XR® after continued use may precipitate acute withdrawal reactions, which can be life-threatening. To reduce the risk of withdrawal reactions, use a gradual taper to discontinue Loreev XR® or reduce the dosage

APPENDIX D: General Information

- CNS Depression: May cause CNS depression. Caution patients receiving Loreev XR® against operating machinery or driving a motor vehicle as well to avoid the concomitant use of alcohol and other CNS depressant drugs during treatment.
- Patients with Depression or Psychosis: Use with caution in patients with signs or symptoms of depression.

Prescribe the least number of tablets feasible to avoid intentional overdosage.

- Neonatal Sedation and Withdrawal Syndrome: Use of Loreev XR® during pregnancy can result in neonatal sedation and/or withdrawal.
- For dosage adjustments, discontinue Loreev XR® and switch to lorazepam tablets to adjust dosage.

References

1. Loreev XR® (lorazepam) capsule prescribing information. Morristown, NJ: Almatica Pharma LLC; February 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=227734c1-bf01-9607-73ea-5a1f38a89bd9&type=display. Accessed October 4, 2021.
2. Loreev XR®: IPD Analytics - Pharma Market Insights. Ipdanalytics.com. Available at: https://secure.ipdanalytics.com/User/Pharma/Drug/Loreev-XR®. Accessed October 4, 2021.
3. Lorazepam: LexiComp. Lexi.com. Available at: https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/7195?cesid=9CkiWzYZURu&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dativan%26t%3Dname%26va%3Dativan. Accessed October 4, 2021.
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5. Lorazepam: Clinical Pharmacology powered by ClinicalKey. Tampa, FL: Elsevier, 2021. Available at: http://www.clinicalkey.com. Accessed October 4, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	10/04/2021	12/07/2021