Effective Date **1/15/2024**
Next Review Date… **1/15/2025**
Coverage Policy Number **IP0364**

Lorazepam Extended-Release

Table of Contents

Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy addresses the usage of lorazepam extended-release capsules (**Loreev XR®**).

Conditions Not Covered

Lorazepam extended-release capsule (Loreev XR) is not covered for the treatment of anxiety disorders or for ANY other use because it is considered not medically necessary.

Loreev XR has no advantage in safety or efficacy over the immediate release formulation and is therefore primarily for the convenience of the individual.

Loreev XR is a once-daily dosing formulation of lorazepam that requires an individual to be stable and compliant, with evenly divided, three times daily dosing of immediate release lorazepam tablets per the product's prescribing information. Since compliance is necessary for transition to the once-daily option (Loreev XR), the use of this medication is considered primarily for the convenience of the individual, and is not medically necessary for ANY use, including treatment of anxiety disorder.

Additionally, Loreev XR was approved through the 505(b)(2) pathway and, as such, relied upon existing safety and efficacy information for immediate release lorazepam to support approval. No clinical efficacy studies were

undertaken with Loreev XR. Other long-acting benzodiazepine options are available if needed, for example alprazolam XR.

Background

OVERVIEW

Lorazepam tablets and oral concentrate are indicated for the **management of anxiety disorders** or for the **short-term relief of the symptoms of anxiety or anxiety-associated with depressive symptoms**.[1,2] Loreev XR is indicated for the treatment of **anxiety disorders in adults who are receiving stable, evenly divided, three times daily dosing with lorazepam tablets**.[3] The effectiveness of lorazepam tablets, lorazepam oral concentrate, or Loreev XR for more than 4 months has not been assessed in clinical studies. Healthcare providers should periodically re-evaluate longer term use of lorazepam.

Loreev XR Dosing

In patients who are being treated with lorazepam tablets administered three times daily in evenly divided doses, the recommended once daily dosage of Loreev XR is equal to the total daily dose of lorazepam tablets.[3] For example, for a patient who has been receiving lorazepam tablets 1 mg three times daily, the recommended dose of Loreev XR is 3 mg once daily in the morning. If the clinical response to Loreev XR is inadequate and the patient requires a dose increase, Loreev XR should be discontinued and the patient switched back to lorazepam tablets to increase the dose. Once an adequate clinical response is achieved with a stable, evenly divided three times daily dose of lorazepam tablets, then Loreev XR may be resumed at a once daily dose equivalent. When discontinuing Loreev XR or reducing the dose, gradually taper to reduce the risk of withdrawal reactions.

References

1. Ativan® tablets [prescribing information]. Bridgewater, NJ: Bausch; February 2021.
2. Lorazepam oral concentrate [prescribing information]. Glasgow, KY: Amneal; March 2021.
3. Loreev XR™ extended-release capsules [prescribing information]. Morristown, NJ: Almatica; February 2022.

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. © 2023 Cigna.