



Effective Date: 2/1/2023
Last Approval/Version: 01/2024
Next Review Due By: 01/2025
Policy Number: C24664-A

Benzodiazepine Global Criteria, IL Medicaid Only

PRODUCTS AFFECTED

alprazolam, alprazolam ER, alprazolam XR, Ativan, chlordiazepoxide, clorazepate, diazepam, lorazepam, Loreev XR, oxazepam, Tranxene-T, Valium, Xanax, Xanax XR

COVERAGE POLICY

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

This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Anxiety, alcohol withdrawal syndrome treatment, focal onset seizures, muscle spasms, seizures

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review.

A. SEIZURES

1. Documentation the requested drug is being used for a diagnosis of seizure

B. ALL OTHER INDICATIONS (excluding seizures)

1. (a) Requested drug is being used for an FDA-approved indication
OR
(b) Requested drug is being used for a medically accepted indication that is supported by

Drug and Biologic Coverage Criteria

information from the appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.)

NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy

AND

2. (a) FOR NON-PREFERRED/NON-FORMULARY IMMEDIATE ACTING PRODUCTS:
Documentation that the member had an adequate trial and therapeutic failure or documented serious side effects to up to 3 (three) preferred/formulary ORAL immediate acting products at maximally tolerated doses
OR
(b) FOR LONG-ACTING PRODUCTS:
Documentation that the member had an adequate trial (MINIMUM OF 2 WEEKS) and therapeutic failure or documented serious side effects to ONE ORAL immediate acting product
AND
3. IF NON-FORMULARY/NON-PREFERRED LONG-ACTING PRODUCT REQUEST:
Documentation that the member had an adequate trial (MINIMUM OF 2 WEEKS) and therapeutic failure or documented serious side effects to ONE formulary/preferred LONG-ACTING PRODUCT
AND
4. (a) Documentation of medical necessity for use of benzodiazepines beyond 14 days [DOCUMENTATION REQUIRED]
OR
(b) Prescriber attests or reviewer has found evidence the member has received a benzodiazepine in the last 60 days.

CONTINUATION OF THERAPY:

A. SEIZURE:

1. Documentation the requested drug is being used for a diagnosis of seizure

B. ALL OTHER INDICATIONS (excluding seizures):

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms

DURATION OF APPROVAL:

Seizures: 12 months

Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

None

AGE RESTRICTIONS:

All drugs must be prescribed within FDA indicated age range or compendia supported age range.

Maximum Quantity Limits – Based on FDA label or compendia supported quantity limits

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PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral

DRUG CLASS:

Benzodiazepines

FDA-APPROVED USES:

Refer to individual product

COMPENDIAL APPROVED OFF-LABELED USES:

UpToDate, Micromedex, AHFS or Clinical Pharmacology

APPENDIX

APPENDIX: None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND: None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of benzodiazepines are considered experimental/investigational and therefore, will follow Molina's Off- Label policy.

OTHER SPECIAL CONSIDERATIONS:

Food and Drug Administration (FDA) Black Box warning on concomitant use with opioids: Food and Drug Administration (FDA) black box warning: Health care professionals should limit prescribing opioid pain medicines with benzodiazepines or other central nervous system (CNS) depressants only to patients for whom alternative treatment options are inadequate. If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect.

Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation and the associated signs and symptoms. Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other central nervous system (CNS) depressants, including alcohol.

www.fda.gov/Drugs/DrugSafety/ucm518473.htm

AVAILABLE DOSAGE FORMS

alprazolam, alprazolam ER, alprazolam XR, Ativan, chlordiazepoxide, clorazepate, diazepam, lorazepam, Loreev XR, oxazepam, Tranxene-T, Valium, Xanax, Xanax XR

REFERENCES

1. Illinois Medicaid Preferred Drug List, Effective January 1, 2024
2. Xanax (alprazolam) tablet [package insert]. New York, NY: Pharmacia & Upjohn Company; January 2023.
3. Xanax XR (alprazolam) extended-release tablet [package insert]. New York, NY: Pharmacia & Upjohn Company; January 2023.
4. Ativan (lorazepam) tablets [package insert]. Bridgewater, NJ: Bausch Health US, LLC; January 2023.
5. Loreev XR (lorazepam) extended-release capsules [package insert]. Morristown, NJ: Almatica Pharma, LLC; January 2023.
6. Chlordiazepoxide hydrochloride capsules [package insert]. Cranbury, NJ: Solco Healthcare U.S. LLC; January 2023.
7. Tranxene (clorazepate) package insert. Lebanon, NJ: Recordati Rare Diseases; January 2023.
8. Valium (diazepam) tablet package insert. Wixom, MI: Waylis Therapeutics, LLC; October 2023.
9. Oxazepam capsule package insert. Parsippany, NJ: Actavis Pharma, Inc.; August 2022.
10. Illinois Department of Healthcare and Family Services; Provider Notice Issued 12/19/2022: <https://hfs.illinois.gov/medicalproviders/notices/notice.prn221219a.html>

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW. Notable revisions: References	01/2024
Q1 2023 Established new policy for IL Medicaid Only	01/2023