Clinical Policy: Doxepin (Silenor)

Reference Number: IL.ERX.PMN.175
Effective Date: 06.01.21
Last Review Date: 11.21
Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Doxepin (Silenor®) is a tricyclic antidepressant.

FDA Approved Indication(s)
Silenor is indicated for treatment of insomnia characterized by difficulties with sleep maintenance.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions that Silenor is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of insomnia;
2. Age ≥ 18 years;
3. Failure of zolpidem, unless age 65 years and older, contraindicated, or clinically significant adverse effects are experienced;
4. Dose does not exceed 6 mg per day (1 tablet per day).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 6 mg per day (1 tablet per day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
zolpidem (Ambien®)	Adults: 5-10 mg PO QHS Elderly: 5 mg PO QHS	10 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Individuals who have shown hypersensitivity to doxepin HCl, any of its inactive ingredients, or other dibenzoxepines
  - Co-administration with monoamine oxidase inhibitors (MAOIs)
  - Patients with untreated narrow angle glaucoma or severe urinary retention

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Insomnia	Adults: 6 mg PO HS PRN Elderly: 3 mg PO HS PRN	6 mg/day

VI. Product Availability
Tablets: 3 mg, 6 mg

VII. References
1. Silenor Prescribing Information. Morristown, NJ: Pernix Therapeutics, LLC, Inc. October 2020. Available at: https://www.silenor.com. Accessed July 21, 2021.
2. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017;13(2):307–349.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.15.21	05.21
4Q 2021 annual review: no significant changes; references reviewed and updated.	07.21.21	11.21

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.