RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	doxepin
Policy Number:	RxA.479
Drug(s) Applied:	Silenor®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Doxepin (Silenor®) is a tricyclic antidepressant. It is indicated for treatment of insomnia characterized by difficulties with sleep maintenance.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
doxepin (Silenor®)	Insomnia	Adults: 6 mg PO HS PRN Elderly: 3 mg PO HS PRN	6 mg/day

Dosage Forms

- Tablets: 3 mg, 6 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.

I. Initial Approval Criteria

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

1. Diagnosis of insomnia;
2. Age ≥ 18 years;
3. Failure of zolpidem or zolpidem CR, unless member meets one of the following (a, b, or c):
   a. Age ≥ 65 years;
   b. Contraindicated or clinically significant adverse effects are experienced;
   c. Member has a previous history of substance abuse;
4. Dose does not exceed 6 mg (1 tablet) per day.

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met

initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 6 mg (1 tablet) per day.

Approval duration
Commercial: 12 months
Medicaid:12 months

III. Appendices

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	Maximum Dose
zolpidem (Ambien®)	Adults: 5-10 mg PO QHS Elderly: 5 mg PO QHS	10 mg/day
zolpidem extended release (Ambien CR®)	Adults: 6.25-12.5 mg PO QHS Elderly: 6.25 mg PO QHS	12.5 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
  - Concomitant use with monoamine oxidase inhibitors (MAOIs)
  - Patients with untreated narrow angle glaucoma or severe urinary retention
- Boxed warning(s):
  - None reported

APPENDIX D: General Information

- None

References

1. Silenor® Prescribing Information. Morristown, NJ: Pernix Therapeutics, LLC, Inc. August 2019. Available at: https://www.silenor.com. Accessed September 3, 2020.
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. Accessed September 3, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed:	09/03/2020	12/07/2020

1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Commercial approval duration was updated from Length of benefit, to 6 months for Initial, and to 12 months for continued approval criteria. 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. References were updated.		