Clinical Policy: Suvorexant (Belsomra)

Reference Number: IL.ERX.PMN.109
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

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

Description

Suvorexant (Belsomra®) is an orexin receptor antagonist.

FDA Approved Indication(s)

Belsomra is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Belsomra 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 two preferred or formulary agents indicated for insomnia (*see Appendix B for examples*) at maximally indicated doses, each tried for ≥ 14 days, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 20 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 health 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 20 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 health 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
temazepam (Restoril®)	Adults: 15 – 30 mg PO HS PRN Elderly: 7.5 – 15 mg PO HS PRN	30 mg/day
trazodone (Desyrel®)	Adults: 50 – 100 mg PO HS PRN Elderly: 25 – 50 mg PO HS PRN	100 mg/day
triazolam (Halcion®)	0.25 mg PO HS PRN	0.5 mg per day
zolpidem IR (Ambien®)	5 mg PO HS PRN	10 mg per 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.
Formulary status may differ based on line of business and health plan verify formulary status prior to redirection.

Appendix C: Contraindications/Boxed Warnings

- Belsomra is contraindicated in patients with narcolepsy.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Insomnia	10 mg PO HS PRN If the 10 mg dose is well-tolerated but not effective, the dose can be increased, not to exceed 20 mg once daily.	20 mg/day

VI. Product Availability

Tablets: 5 mg, 10 mg, 15 mg, 20 mg

VII. References

1. Belsomra Prescribing Information. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; March 2020. Available at https://www.belsomra.com/ Accessed July 23, 2020.
2. Qaseem A, Kansagara D, Forciea MA, Cooke M, Denberg TD, for the Clinical Guidelines Committee of the American College of Physicians. Management of chronic insomnia disorder in adults: A clinical practice guideline from the American College of Physicians. Ann Intern Med. 2016;165:125-133.
3. 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

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.