Sedative Hypnotics

Policy # 00359
Original Effective Date: 08/21/2013
Current Effective Date: 08/15/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider brand name sedative hypnotics including, but not limited to Edluar®‡ (zolpidem sublingual), Intermezzo®‡ (zolpidem sublingual), Lunesta®‡ (eszopiclone), Rozerem®‡ (ramelteon), Silenor®‡ (doxepin), Sonata®‡ (zaleplon), Ambien®‡/Ambien CR®‡ (zolpidem), Zolpimist®‡ (zolpidem oral spray) and Belsomra®‡ (suvorexant) to be **eligible for coverage** when one of the below patient selection criteria is met:

Patient Selection Criteria
Coverage eligibility for brand name sedative hypnotics will be considered when one of the following criteria is met:

- Requested drug is ANY brand name sedative hypnotic: There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient; OR
- Requested drug is ANY brand name sedative hypnotic: Patient has tried and failed a generic sedative hypnotic (e.g. generic zolpidem immediate release, generic zolpidem extended release, generic zolpidem sublingual tablets, generic zaleplon, or generic eszopiclone); OR
- Requested drug is Rozerem: Patient has a documented history of addiction to controlled substances OR is 65 years of age or older; OR
- Requested drug is Silenor: Patient has a documented history of addiction to controlled substances.

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of brand name sedative hypnotics when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary.****

Background/Overview

Sedative hypnotics encompass drugs with various mechanisms of action. Drugs such as zolpidem (Ambien, Ambien CR, Edluar, Intermezzo, and Zolpimist), zaleplon, and Lunesta interact with the gamma-aminobutyric acid (GABA) receptor complexes located near the benzodiazepine receptors. These agents are Schedule IV controlled substances. Belsomra is a first in class orexin receptor antagonist and is also a Schedule IV substance. Rozerem is a melatonin receptor agonist and Silenor is a tricyclic compound that acts as an H1 receptor antagonist. Neither Rozerem nor Silenor are controlled substances. Rozerem's

unique mechanism of action may be beneficial for older patients with or at risk for memory/cognitive/psychomotor impairment.

Rationale/Source

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the available generic sedative hypnotics will be ineffective or cause an adverse reaction to the patient. This policy also takes into consideration the patient's age and whether or not the patient has a documented history of addiction to controlled substances. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using a brand name sedative hypnotic over the available generic sedative hypnotics. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

References

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Policy History

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08/01/2013	Medical Policy Committee review
08/21/2013	Medical Policy Implementation Committee approval. New policy.
08/07/2014	Medical Policy Committee review
08/20/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/06/2015	Medical Policy Committee review
08/19/2015	Medical Policy Implementation Committee approval. Added Belsomra (suvorexant) to the policy.
08/04/2016	Medical Policy Committee review
08/17/2016	Medical Policy Implementation Committee approval. Added a new brand, Zolpimist, to the policy. Added a new generic, zolpidem sublingual tablets, to the policy
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 08/2019

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.