



Uniform Formulary Medical Necessity Criteria for Newer Sedative Hypnotic Agents

Drug Class - Newer Sedative Hypnotics. This drug class includes Ambien (zolpidem immediate release), Ambien CR (zolpidem extended release), Lunesta (eszopiclone), Rozerem (ramelteon), and Sonata (zaleplon).

Background - After evaluating the relative clinical and cost effectiveness of the newer sedative hypnotics, the DoD P&T Committee recommended that the following medications be designated as non-formulary. This recommendation has been approved by the Director, TMA.

- Ambien CR (zolpidem extended release)
- Rozerem (ramelteon)
- Sonata (zaleplon)

Effective Date: 1 August 2007

Patients currently using a nonformulary agent may wish to ask their doctor to consider a formulary alternative.

Uniform Formulary Status, Cost shares, and Therapeutic Alternatives for Newer Sedative Hypnotic Agents^{1,2}

Uniform Formulary Status	Medication	MTF (up to a 90 day supply)	TMOP (up to a 90 day supply)	Retail (up to a 30-day supply)
Non-Formulary (Tier 3)	Ambien CR, Rozerem, Sonata, Edluar	Not available ²	Non-Formulary cost share applies	Non-Formulary cost share applies
Formulary (Tier 2)	Ambien, Lunesta	\$0	Formulary (Brand) cost share applies	Formulary (Brand) cost share applies
Generic (Tier 1)	Zolpidem IR	\$0	Generic cost share applies	Generic cost share applies
<p>1. Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover nonformulary medications for active duty service members unless they are determined to be medically necessary.</p> <p>2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.</p>				

Special Notes

[Step therapy / prior authorization \(PA\) requirements](#) apply to all drugs in this class except zolpidem immediate release (Ambien), effective 1 August 2007. The medical necessity form may NOT be used to meet PA requirements.

Medical Necessity Criteria

The non-formulary cost share for Ambien CR, Rozerem, or Sonata may be reduced to the formulary cost share if the patient meets any of the following criteria.

1. Use of both of the following formulary alternatives is contraindicated (e.g., due to hypersensitivity): zolpidem immediate release (Ambien) and eszopiclone (Lunesta).
2. The patient has experienced or is likely to experience significant adverse effects from both of the following formulary alternatives: zolpidem immediate release (Ambien) and eszopiclone (Lunesta).
3. Use of both of the following formulary alternatives has resulted in therapeutic failure: zolpidem immediate release (Ambien) and eszopiclone (Lunesta).
4. **(Rozerem only)** Rozerem, which is a non-controlled drug with a mechanism of action different from other newer sedative hypnotics, is the most clinically suitable choice for the patient due to its apparent lack of abuse potential.
5. **(Edluar only)** Patient has documented swallowing difficulty and requires Edluar (zolpidem sublingual) because it may be dissolved under the tongue rather than swallowed whole.

Medical necessity criteria for Ambien CR, Rozerem, and Sonata recommended by the DoD Pharmacy & Therapeutics Committee and approved by the Director, TMA. For more information, please see the February 2007 and February 2010 [DoD P&T Committee minutes](#).

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