UnitedHealthcare Individual & Family ACA Marketplace Plans
Clinical Pharmacy Program Guidelines for Sedative Hypnotic Agents

Program	Step Therapy
Medication	Ramelteon (generic Rozerem), Belsomra (suvorexant)
Issue Date	9/2020
Pharmacy and Therapeutics Approval Date	7/2023
Effective Date	9/2023

1. Background:

Ramelteon (generic Rozerem) is a sedative hypnotic agent indicated for the treatment of sleep-onset insomnia. Belsomra (suvorexant) is a sedative hypnotic agent indicated for treatment of both sleep-onset and sleep-maintenance insomnia.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try alternative sedative hypnotic agents prior to receiving coverage for Ramelteon (generic Rozerem) or Belsomra (suvorexant).

2. Coverage Criteria[a]:

A. Belsomra will be approved based on the following criterion:

1. History of trial and failure, contraindication, or intolerance to **two** of the following sedative-hypnotic alternatives:

   a. Zolpidem immediate release tablets (generic Ambien)
   b. Zaleplon (generic Sonata)
   c. Eszopiclone (generic Lunesta)

   Authorization will be issued for 12 months.

B. Ramelteon (generic Rozerem) will be approved based on **one** of the following criteria:

1. History of trial and failure, contraindication, or intolerance to **two** of the following sedative-hypnotic alternatives:

   a. Zolpidem immediate release tablets (generic Ambien)
   b. Zaleplon (generic Sonata)
   c. Eszopiclone (generic Lunesta)

-OR-

2. History of or potential for a substance abuse disorder

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Other Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits may be in place.

4. References:

1. Belsomra [package insert]. Whitehouse Station, NJ. Merck & Co; February 2023.
2. Rozerem [package insert]. Deerfield, IL. Takeda Global; November 2021.

Program	Step Therapy – Sedative Hypnotic Agents
Change Control	
Date	Change
4/2014	With the 7/1/14 exclusion of zolpidem ER, removed criteria C, and added Ambien CR, zolpidem extended-release and Intermezzo to criteria A. Updated references.
11/2014	Added eszopiclone as first step agent. Revised to require trial of two of the three first step agents.
2/2015	Removed Ambien, Ambien CR, Edluar, Intermezzo, Lunesta and Sonata from step therapy program. Added criteria for Belsomra.
5/2015	Revised Oxford implementation date.
2/2016	Annual Review. Updated references.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
3/2017	Annual review. Updated references. State mandate reference language updated.
3/2018	Annual review. Updated references.
3/2019	Annual review. Updated references.
4/2020	Annual review. Updated references.
10/2020	Revised background, removed Zolpimist as a target drug, removed brand Rozerem as a target drug, and revised zolpidem alternative formulation on formulary.
11/2020	Updated ST Descriptions and alternatives to align build file and set up for UHC Value & Balance Exchange for 1/2021 implementation.
9/2021	Updated references. Removed automation language.
5/2022	Annual review. Updated references.

7/2023	Annual review, updated reference.