UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 3024-18
Program	Step Therapy
Medication/Therapeutic Class	Sedative Hypnotic Agents: Belsomra® (suvorexant), DayVigo® (lemborexant), Quviviq®* (daridorexant), Rozerem®* (ramelteon)
P&T Approval Date	8/2008, 8/2009, 12/2009, 11/2010, 7/2011, 4/2012, 4/2013, 4/2014, 11/2014, 2/2015, 2/2016, 3/2017, 3/2018, 3/2019, 4/2020, 10/2020, 5/2021, 5/2022, 11/2022, 1/2024, 3/2025
Effective Date	6/1/2025

1. Background:

Step Therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try a lower cost sedative hypnotic agent before providing coverage for Belsomra, DayVigo, Quviviq*, or Rozerem*. If a member has a prescription for two of the first step sedative hypnotics in claims history within the previous 12 months, the prescription for Belsomra, DayVigo, or ramelteon will automatically process.

2. Coverage Criteria[a]:

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

1. History of trial and failure of at least 2 weeks, contraindication, or intolerance to **two** of the following sedative-hypnotic alternatives:

   a. Zolpidem (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 of at least 2 weeks, contraindication, or intolerance to **two** of the following sedative-hypnotic alternatives:

   a. Zolpidem (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.

C. Rozerem* will be approved based on **one** of the following criteria:

1. **Both** of the following:

   a. History of trial and failure of at least 2 weeks, contraindication, or intolerance to **two** of the following sedative-hypnotic alternatives:

      (1) Zolpidem (generic Ambien)
      (2) Zaleplon (generic Sonata)
      (3) Eszopiclone (generic Lunesta)

-AND-

   b. History of trial and failure of at least 2 weeks, contraindication, or intolerance to ramelteon (generic Rozerem)

-OR-

2. **Both** of the following:

   a. History of or potential for a substance abuse disorder

-AND-

   b. History of trial and failure of at least 2 weeks, contraindication, or intolerance to ramelteon (generic Rozerem)

Authorization will be issued for 12 months.

D. Quviviq* will be approved based on **both** the following criteria:

1. History of trial and failure of at least 2 weeks, contraindication, or intolerance to **both** of the following:

   a. Belsomra
   b. DayVigo

-AND-

2. History of trial and failure of at least 2 weeks, contraindication, or intolerance to **two** of the following:

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

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.

*Brand Rozerem and Quviviq are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

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; March 2023.
2. Rozerem [package insert]. Deerfield, IL: Takeda Global; January 2023.
3. DayVigo [package insert]. Nutley, NJ: Easai Inc; December 2023.
4. Quviviq [package insert]. Radnor, PA: Idorsia Pharmaceuticals Ltd; September 2024.

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	Added DayVigo to criteria.
5/2021	Updated criteria to note brand Rozerem is typically excluded from coverage and will require a step through the generic. Updated references.
5/2022	Annual review. Updated references.
11/2022	Quviviq added to criteria.
1/2024	Annual review. Removed Zolpimist from step therapy program since this product is no longer on the market.
3/2025	Annual review. Updated references.