UnitedHealthcare

One UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 3024-16
Program	Step Therapy
Medication/Therapeutic Class	Sedative Hypnotic Agents: Belsomra (suvorexant), DayVigo (lemborexant), Quviviq* (daridorexant), Rozerem* (ramelteon), Zolpimist (zolpidem tartrate)
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
Effective Date	5/1/2023; Oxford only: 5/1/2023

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*, Rozerem*, or Zolpimist. 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, ramelteon, or Zolpimist will automatically process.

2. Coverage Criteria[a]:

A. Belsomra, DayVigo or Zolpimist 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.

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.
- *Brand Rozerem and Quviviq are typically excluded from coverage.

4. References:

1. Belsomra [package insert]. Whitehouse Station, NJ: Merck & Co; March 2021.
2. Rozerem [package insert]. Deerfield, IL: Takeda Global; November 2021.
3. Zolpimist [package insert]. Englewood, CO: Aytu BioScience, Inc; August 2019.
4. DayVigo [package insert]. Nutley, NJ: Easai Inc; March 2022.
5. Quviviq [package insert]. Radnor, PA: Idorsia Pharmaceuticals Ltd; April 2022.

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.