Reference number(s)
7574-A

Specialty Guideline Management Orzeyful

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Orzeyful	oveporexton

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Orzeyful is indicated for the treatment of narcolepsy type 1 (narcolepsy with cataplexy) in adult patients.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review

Initial requests

- Documentation of a sleep lab evaluation.
- Mean sleep latency on multiple sleep latency test (MSLT) of less than or equal to 8 minutes.
- MSLT showing two or more sleep-onset REM periods (SOREMPs) on MSLT or a SOREMP (within 15 minutes of sleep onset) on nocturnal polysomnogram.

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- If sleep lab evaluation or results are unavailable, laboratory test or medical record documentation of cerebrospinal fluid (CSF) orexin/hypocretin-1 level.

Continuation requests

- Chart notes or medical record documentation supporting a beneficial response to therapy as demonstrated by a decrease in daytime sleepiness from baseline or decrease in cataplexy episodes from baseline.

Prescriber Specialties

This medication must be prescribed by or in consultation with a sleep specialist (e.g., neurologist experienced with sleep disorders, physician certified in sleep medicine).

Coverage Criteria[1,2]

Authorization of 12 months may be granted for adult members for treatment of narcolepsy type 1 (NT1) when all of the following criteria are met:

- The member has daily periods of irrepressible need to sleep or daytime lapses into drowsiness or sleep.
- The member meets either of the following criteria:
    - Member meets both of the following criteria:
        - Member has a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) or a SOREMP (within 15 minutes of sleep onset) on nocturnal polysomnogram.
        - Member has cataplexy.
    - Member has a cerebrospinal fluid (CSF) orexin/hypocretin-1 level less than or equal to 110 picograms per milliliter (pg/mL) or less than one-third of mean values obtained in normal subjects with the same standardized assay.
- The member's signs and symptoms are not better explained by chronic insufficient sleep, a circadium rhythm sleep-wake disorder, or other current sleep disorder, mental disorder, or medication/substance use or withdrawal.

Continuation of Therapy

Authorization of 12 months may be granted for adult members for continued treatment of narcolepsy type 1 (NT1) when the member has demonstrated beneficial response to treatment as defined by a decrease in daytime sleepiness from baseline or decrease in cataplexy episodes from baseline.

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References

1. Orzeyful [package insert]. Cambridge, MA: Takeda Pharmaceuticals America, Inc.; August 2026.
2. American Academy of Sleep Medicine. International Classification of Sleep Disorders. 3rd ed., Text Revision (ICSD-3-TR). Darien, IL: American Academy of Sleep Medicine; 2023.

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