

# New Hampshire Medicaid Fee-for-Service Program Wakix® (pitolisant) Criteria

Approval Date: November 21, 2024

## Medications

Brand Names	Generic Names	Indication
Wakix®	pitolisant	Treatment of excessive daytime sleepiness (EDS) in adults and pediatric patients 6 years of age and older with narcolepsy

## Criteria for Approval

1. Patient is 6 years of age or older; **AND**
2. Prescribed by or in consultation with a sleep specialist or neurologist; **AND**
3. The patient has a diagnosis of narcolepsy according to International Classification of Sleep Disorders (ICSD-3) or Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria; **AND**
4. The patient has excessive daytime sleepiness associated with narcolepsy as confirmed by documented sleep testing (e.g., polysomnography, multiple sleep latency test); **AND**
5. Other causes for hypersomnolence have been ruled out, such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal; **AND**
6. Patient has daily periods of irrepensible need to sleep or daytime lapses into sleep occurring for 3 months or more; **AND**
7. Patient has tried for a period of at least 30 days and failed at least one CNS stimulant drug (e.g., methylphenidate) or has a contraindication to stimulant use; **AND**
8. Patient has tried for a period of at least 30 days and failed at least one central nervous system (CNS)-promoting wakefulness drug (e.g., modafinil) or has a contraindication to use; **AND**
9. Sleep logs have been submitted for the last 30 days.

**Initial approval period:** 6 months

**Renewal period:** 12 months

## Criteria for Denial

1. Failure to meet approval criteria; **OR**
2. Patient has a history or risk factor for prolonged QT interval; **OR**

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3. Patient is receiving treatment with sedative hypnotic agents (e.g., zolpidem, eszopiclone, zaleplon, benzodiazepines, barbiturates).

## Criteria for Renewal

1. Clinical response to therapy submitted (supporting documentation required); **AND**
2. Patient has not experienced any treatment-restricting adverse events.

## References

Available upon request.

## Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	05/07/2024
Commissioner designee	Approval	06/10/2024
DUR Board	Revision	10/15/2024
Commissioner designee	Approval	11/21/2024