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

Approval Date: June 10, 2024

Medications

Brand Names	Generic Names	Indication
Wakix®	**pitolisant**	Treatment of excessive daytime sleepiness (EDS) in adults with narcolepsy

Criteria for Approval

1. Patient is 18 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 irrepressible 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**
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