

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1298-7
Program	Prior Authorization/Notification
Medication	Wakix® (pitolisant)
P&T Approval Date	10/2019, 3/2021, 3/2022, 3/2023, 3/2024, 9/2024, 9/2025
Effective Date	11/16/2025

1. Background:

Wakix is a histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adults with narcolepsy and EDS in pediatric patients 6 years of age and older with narcolepsy.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria^a:

A. Narcolepsy

1. Initial Authorization

a. **Wakix** will be approved based on **both** of the following criteria:

- (1) Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)²

–AND–

- (2) Symptoms of **ONE** of the following are present:

- (a) excessive daytime sleepiness (including but not limited to daily periods of irrepressible need to sleep or daytime lapses into sleep)
- (b) cataplexy

Authorization will be issued for 12 months.

2. Reauthorization

a. **Wakix** will be approved for continuation of therapy based on the following criterion:

- (1) Reduction in symptoms of excessive daytime sleepiness or cataplexy associated with Wakix therapy

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. Additional Clinical Rules:

- 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, Medical Necessity may be in place.

4. References:

1. Wakix [package insert]. Plymouth Meeting, PA: Harmony Biosciences, LLC; June 2025.
2. American Academy of Sleep Medicine. International Classification of Sleep Disorders: Diagnostic and Coding Manual. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.
3. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: An American Academy of Sleep Medicine clinical practice guideline. Journal of Clinical Sleep Medicine. 2021. Sept (17):1881-1893.

Program	Prior Authorization/Notification - Wakix® (pitolisant)
Change Control	
10/2019	New program
3/2021	Updated to include coverage for narcolepsy with cataplexy based on new product labeling.
3/2022	Annual review. Updated references.
3/2023	Annual review. Updated references. Added state mandate language.
3/2024	Annual review. No changes.
9/2024	Updated initial authorization to 12 months. Updated references.
9/2025	Annual review. Updated references.