

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2174-8
Program	Prior Authorization/Medical Necessity
Medication	Wakix® (pitolisant)
P&T Approval Date	10/2019, 12/2019, 4/2020, 3/2021, 6/2021, 6/2022, 10/2023, 9/2024
Effective Date	12/1/2024

1. Background:

Wakix is a histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult and 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 without Cataplexy (i.e., Narcolepsy Type 2)

1. Initial Authorization

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

(1) Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy with **both** of the following:

(a) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.

(b) A mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT.

-AND-

(2) Physician attestation to the following:

(a) Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders).

-AND-

(3) **One** of the following:

(a) History of failure, contraindication, or intolerance to **all** of the following:

(i) armodafinil (Nuvigil) or modafinil (Provigil)

(ii) an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

(iii) Sunosi

-OR-

(b) History of or potential for a substance abuse disorder

-AND-

(4) Prescribed by or in consultation with **one** of the following:

(a) Neurologist

(b) Psychiatrist

(c) Pulmonologist

(d) Sleep Medicine Specialist

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 associated with Wakix therapy

Authorization will be issued for 12 months.

B. Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)

1. **Initial Authorization**

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

(1) Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy *with* cataplexy (i.e., Narcolepsy Type 1) with **both** of the following:

(a) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.

(b) A mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT.

-AND-

(2) Physician attestation to **both** of the following:

(a) Patient has experienced cataplexy defined as more than one episode of sudden loss of muscle tone with retained consciousness

-AND-

(b) Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders).

-AND-

(3) Prescribed by or in consultation with **one** of the following:

- (a) Neurologist
- (b) Psychiatrist
- (c) Pulmonologist
- (d) Sleep Medicine Specialist

Authorization will be issued for 12 months.

2. Reauthorization

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

- (1) Reduction in frequency of cataplexy attacks associated with therapy

–OR–

- (2) Reduction in symptoms of excessive daytime sleepiness associated with 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 may be in place.

4. References:

1. Wakix [package insert]. Plymouth Meeting, PA: Harmony Biosciences, LLC; June 2024.
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. Sunosi [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc; October 2021.
4. 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.
5. Wise MS1, Arand DL, Auger RR, et al. Treatment of narcolepsy and other hypersomnias of central origin. *Sleep*. 2007 Dec;30(12):1712-27.

Program	Prior Authorization/Medical Necessity - Wakix® (pitolisant)
Change Control	
11/2019	New program
12/2019	Added requirement for history of Sunosi.
4/2020	Added requirement for submission of documentation of sleep study with specific sleep study requirements. Added requirement for

	prescriber specialty. Changed initial authorization duration to 12 months.
3/2021	Added criteria for narcolepsy with cataplexy based on updated product labeling.
6/2021	Updated Type 1 narcolepsy section to clarify that medical records submitted show narcolepsy with cataplexy and provider attestation for cataplexy symptoms. Added pulmonologist to the list of specialists.
6/2022	Annual review. Updated references.
10/2023	Annual review. Updated references.
9/2024	Annual review. Updated references.