

## Commercial/Healthcare Exchange PA Criteria

*Effective: November 13, 2019*

**Prior Authorization:** Wakix

**Products Affected:** Wakix (pitolisant) oral tablets

**Medication Description:**

Wakix is an antagonist/inverse agonist of the histamine-3 (H3) receptor indicated for the treatment of excessive daytime sleepiness (EDS) in adults with narcolepsy.

**Covered Uses:** Excessive daytime sleepiness associated with narcolepsy

**Exclusion Criteria:**

1. Patients with severe hepatic impairment

**Required Medical Information:**

1. Diagnosis
2. Previous therapies tried and failed

**Age Restrictions:** 18 years of age or older

**Prescriber Restrictions:** Prescribed by or in consultation with a sleep disorder specialist, psychiatrist, or neurologist

**Coverage Duration:** 12 months

**Other Criteria:**

- A. Patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy; **AND**
- B. Patient must have a trial and failure, contraindication, or intolerance to at least one CNS stimulant drug (e.g., methylphenidate, dexamethylphenidate, dextroamphetamine) **AND** at least one CNS wakefulness promoting drug (e.g. armodafinil).

**References:**

1. Wakix® tablets [prescribing information]. Plymouth Meeting, PA: Harmony Biosciences, LLC; August 2019.
2. Sunosi™ tablets [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; March 2019.
3. Provigil® tablets [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2018.
4. Nuvigil® tablets [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2018.
5. Wise MS, Arand DL, Auger R, et al. Treatment of narcolepsy and other hypersomnias of central origin: An American Academy of Sleep Medicine Review. *Sleep*. 2007;30(12):1712-27. Available at: [http://www.aasmnet.org/Resources/PracticeParameters/Review\\_Narcolepsy.pdf](http://www.aasmnet.org/Resources/PracticeParameters/Review_Narcolepsy.pdf). Accessed on September 6, 2019.

6. National Institutes of Health. Narcolepsy Fact Sheet. National Institute of Neurological Disorders and Stroke. Date last modified: August 13, 2019. Available at: <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Narcolepsy-Fact-Sheet>. Accessed on September 6, 2019.

## Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	11/13/2019

