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PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Wakix (pitolisant)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Wakix, approved by the FDA in 2019, is an oral histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy, and for the treatment of excessive daytime sleepiness (EDS) in pediatric patients 6 years of age and older with narcolepsy. Narcolepsy is a chronic neurologic disorder involving dysregulation of the sleep/wake cycle.

Wakix (pitolisant) will be considered for coverage when the following criteria are met:

Narcolepsy with Excessive Daytime Sleepiness (EDS)

For **initial** authorization:

1. Member is at least 6 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist or sleep specialist; AND
3. Member has a diagnosis of narcolepsy confirmed by sleep studies: polysomnogram and MSLT (multiple sleep latency test); AND
4. Member has symptoms of excessive daytime sleepiness (EDS) not attributed to other factors such as insufficient sleep, irregular sleep schedule, co-existent sleep disorder, medications or other substances; AND
5. Member's current score on the Epworth Sleepiness Scale (ESS) OR Pediatric Daytime Sleepiness Scale (PDSS) score is documented in chart notes; AND
6. Member meets one of the following:
   a) Adult: Trial and failure for at least 30 days each: modafinil or armodafinil, AND Sunosi
   b) Pediatric: Trial and failure of at least one of the following for no less than 30 days: modafinil, methylphenidate, amphetamine; AND
7. Member does NOT have any of the following:
   a) Severe hepatic impairment
   b) End stage renal disease
   c) QT interval prolongation or cardiac arrythmia.
8. **Dosage allowed/Quantity limit:**
   Pediatric starting dose: 4.45 mg once daily
   Adult starting dose: 8.9 mg once daily
   Max dose for patients weighing <40 kg: May titrate up to 17.8 mg once daily
   Max dose for patients weighing at least 40 kg and adults: May titrate up to 35.6 mg once daily
   QL: 60 tablets/30 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show the member has an improved score on the ESS or PDSS, and/or chart notes have been provided that show the member has improved signs and symptoms of EDS.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Narcolepsy with Cataplexy

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist or sleep specialist; AND
3. Member must have a diagnosis of narcolepsy with cataplexy confirmed by sleep studies: polysomnogram and MSLT (multiple sleep latency test); AND
4. Member's current score on the Epworth Sleepiness Scale (ESS) and baseline number of cataplexy attacks (e.g., number per week) must be documented; AND
5. Member must have, unless specifically contraindicated, a compliant trial and failure of at least one of the following cataplexy treatments for no less than 30 days: a tricyclic antidepressant (such as clomipramine), serotonin-norepinephrine reuptake inhibitor (such as venlafaxine), or dextroamphetamine; AND
6. Member does NOT have any of the following:
   a) Severe hepatic impairment
   b) End stage renal disease
   c) QT interval prolongation or cardiac arrythmia.
7. **Dosage allowed/Quantity limit:** Start with 8.9 mg once daily. May titrate up to 35.6 mg once daily. QL: 60 tablets/30 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show decreased frequency and/or severity of cataplexy attacks.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Wakix (pitolisant) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/21/2020	New policy for Wakix created.
11/12/2020	Added criteria for label update with cataplexy.
02/01/2021	For cataplexy, changed from trial and failure of 2 antidepressants to 1.
08/15/2024	Transferred to new template. Updated references. Narcolepsy with EDS: Lowered age limit from 18 to 6 and updated dosing (label update); specified step med(s) for peds population (AASM 2021, EAN 2021), added PDSS score option for peds (clinical trial). Cataplexy: Clarified dosing. Added dextroamphetamine as a trial option, removed SSRI (AASM 2021).

References:

1. Wakix [prescribing information]. Harmony Biosciences, LLC; 2024.
2. 2021 Georgia Code Title 33 – Insurance Chapter 20A - Managed Health Care Plans Article 2 - Patient's Right to Independent Review § 33-20A-31 Definitions. Justia US Law. Accessed April 25, 2023. https://law.justia.com/codes/georgia/2021/title-33/chapter-20a/article-2/section-33-20a-31/.
3. Dauvilliers Y, Bassetti C, Lammers GJ, et al: Pitolisant versus placebo or modafinil in patients with narcolepsy: a double-blind, randomised trial. *Lancet Neurol* 2013; 12(11):1068-1075.
4. Dauvilliers Y, Arnulf I, Szakacs Z, Leu-Semenescu S, Lecomte I, Scart-Gres C, Lecomte JM, Schwartz JC; HARMONY III study group. Long-term use of pitolisant to treat patients with narcolepsy: Harmony III Study. *Sleep*. 2019 Oct 21;42(11). pii: zsz174. doi: 10.1093/sleep/zsz174
5. Szakacs Z, Dauvilliers Y, Mikhaylov V, et al. Safety and efficacy of pitolisant on cataplexy in patients with narcolepsy: a randomised, double-blind, placebo-controlled trial. *Lancet Neurol*. 2017;16(3):200-207. doi:10.1016/S1474-4422(16)30333-7
6. Morgenthaler TI, Kapur VK, Brown TM, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin. *Sleep*. 2007;30(12):1705-1711
7. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2021;17(9):1881–1893.
8. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. *J Clin Sleep Med*. 2021;17(9):1895–1945.
9. Bassetti CLA, Kallweit U, Vignatelli L, et al. European guideline and expert statements on the management of narcolepsy in adults and children. *J Sleep Res*. 2021;30(6):e13387. doi:10.1111/jsr.13387

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