

## PHARMACY POLICY STATEMENT

### North Carolina Marketplace

|                     |                              |
|---------------------|------------------------------|
| <b>DRUG NAME</b>    | <b>Wakix (pitolisant)</b>    |
| <b>BENEFIT TYPE</b> | Pharmacy                     |
| <b>STATUS</b>       | 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 arrhythmia.
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 arrhythmia.
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.<br>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).<br>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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