

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

DRUG NAME	Wakix (pitolisant)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 60 tablets per 30 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Wakix (pitolisant) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### NARCOLEPSY WITH EXCESSIVE DAYTIME SLEEPINESS (EDS)

For **initial** authorization:

1. Member is 18 years old or older; 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 sleepiness 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) is documented in chart notes; AND
6. Member has tried and failed or did not tolerate the following, at max tolerated dose, for at least 30 days each: modafinil or armodafinil, AND Sunosi; 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:** Up to 2 tablets per day; max daily dose of 35.6mg (Two 17.8mg tablets once daily).

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must show the member has an improved score on the Epworth sleepiness scale, and/or chart notes have been provided that show the member has improved signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## NARCOLEPSY WITH CATAPLEXY

For **initial** authorization:

1. Member is 18 years old or older; 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 and baseline number of cataplexy attacks must be documented; AND
5. Member must have, unless specifically contraindicated, a compliant trial and failure of at least **two** of the following cataplexy treatments for no less than 30 days each: a tricyclic antidepressant (such as clomipramine), selective serotonin reuptake inhibitor (such as fluoxetine), or serotonin-norepinephrine reuptake inhibitor (such as venlafaxine); 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:** Up to 2 tablets per day; max daily dose of 35.6mg (Two 17.8mg tablets once daily).

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must show decreased frequency and/or severity of cataplexy attacks.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

**CareSource considers Wakix (pitolisant) not medically necessary for the treatment of diseases that are not listed in this document.**

DATE	ACTION/DESCRIPTION
5/21/2020	New policy for Wakix created.
11/12/2020	Added criteria for label update with cataplexy.

### References:

1. Wakix [package insert]. Plymouth Meeting, PA: Harmony Biosciences, LLC; 2020.
2. Wakix. Micromedex Solutions. Greenwood Village, CO: Truven Health Analytics. <http://micromedex.com/>. Updated April 15, 2020. Accessed May 13, 2020.
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. IPD analytics. Accessed May 13, 2020.
6. Leher P, Falissard B. Multiple treatment comparison in narcolepsy: a network meta-analysis. *Sleep*. 2018;41(12). doi:10.1093/sleep/zsy185
7. 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. doi:10.1093/sleep/30.12.1705
8. Scammell TE. Narcolepsy. *N Engl J Med*. 2015;373(27):2654-2662. doi:10.1056/NEJMra1500587
9. 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

Effective date: 04/01/2021

Revised date: 11/12/2020