CareSource

PHARMACY POLICY STATEMENT **Ohio 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 **NOT** MEDICALLY NECESSARY	Click Here

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 arrythmia.
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.

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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 arrythmia.
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:

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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. Lehert 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