Reference number(s)
3176-A

Specialty Guideline Management
Wakix

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Wakix	pitolisant

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication[1]

- Treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy.
- Treatment of excessive daytime sleepiness (EDS) in pediatric patients 6 years of age and older with narcolepsy.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

For initial requests, all of the following (if applicable):

- Documentation of a sleep lab evaluation.

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

For continuation requests, documentation to support one of the following:

- For excessive daytime sleepiness with narcolepsy: chart notes or medical record documentation supporting a beneficial response to therapy as demonstrated by a decrease in symptoms of daytime sleepiness from baseline.
- For cataplexy with narcolepsy: chart notes or medical record documentation supporting a beneficial response to therapy as demonstrated by a decrease in cataplexy episodes from baseline.

Prescriber Specialties

This medication must be prescribed by or in consultation with a sleep specialist (e.g., neurologist experienced with sleep disorders, physician certified in sleep medicine).

Coverage Criteria

Excessive Daytime Sleepiness (EDS) with Narcolepsy[1-6]

Authorization of 12 months may be granted for treatment of excessive daytime sleepiness (EDS) with narcolepsy when all of the following criteria are met:

- The diagnosis of narcolepsy is confirmed by a sleep lab evaluation.
- The member is 6 years to less than 18 years of age and meets either of the following:
    - The member has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate).
    - The member has a contraindication to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate).
- The member is 18 years of age or older and meets either of the following:
    - The member has experienced an inadequate treatment response or intolerance to armodafinil or modafinil.
    - The member has a contraindication to both armodafinil and modafinil.

Cataplexy with Narcolepsy[1,4-5]

Authorization of 12 months may be granted for treatment of cataplexy in adult patients with narcolepsy when both of the following criteria are met:

- The diagnosis of narcolepsy is confirmed by a sleep lab evaluation.
- The member experiences at least 3 cataplexy attacks per week.[C]

Continuation Of Therapy

Excessive Daytime Sleepiness (EDS) with Narcolepsy

Authorization of 12 months may be granted for continued treatment of excessive daytime sleepiness (EDS) with narcolepsy when the member has demonstrated beneficial response to treatment as defined by a decrease in symptoms of daytime sleepiness from baseline.

Cataplexy with Narcolepsy

Authorization of 12 months may be granted for continued treatment of cataplexy with narcolepsy when the member has demonstrated beneficial response to treatment as defined by a decrease in cataplexy episodes from baseline.

References

1. Wakix [package insert]. Plymouth Meeting, PA: Harmony Biosciences, LLC; June 2024.
2. 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 Nov;12(11):1068-75. doi: 10.1016/S1474-4422(13)70225-4. Epub 2013 Oct 7. Accessed March 10, 2020.
3. Fronczek R, Middelkoop HA, van Dijk JG, Lammers GJ. Focusing on vigilance instead of sleepiness in the assessment of narcolepsy: high sensitivity of the Sustained Attention to Response Task (SART). Sleep. 2006 Feb;29(2):187-91. Accessed March 10, 2020.
4. Morgenthaler TI, Vishesh KK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin. Sleep 2007;30(12):1705-11.
5. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed December 5, 2024.
6. Maski K, Trotti LM, Kotagal S, Auger RR, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. Published online September 1, 2021.