| AETNA BETTER HEALTH®<br>Coverage Policy/Guideline | | | | | |
|---|---|---|---|---|---|
| Name: | Wakix | | | Page: | 1 of 3 |
| Effective Date: | 9/16/2024 | | | Last Review Date: | 8/2024 |
| Applies to: | ☐Illinois<br>☒New Jersey<br>☒Pennsylvania Kids | ☐Florida<br>☐Maryland<br>☐Virginia | | ☒Florida Kids<br>☐Michigan<br>☐Kentucky PRMD | |

## Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Wakix under the patient's prescription drug benefit.

## Description:

FDA-Approved Indication

A. Wakix is indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy.
B. Wakix is indicated for the 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.

## Applicable Drug List:

Wakix

## Policy/Guideline:

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

A. For initial requests, all of the following (if applicable):
    1. Documentation of a sleep lab evaluation.
    2. 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.
B. For continuation requests: documentation to support one of the following:
    1. 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.
    2. 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 Specialty**
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).

**Criteria for Initial Approval:**

**A. Excessive Daytime Sleepiness with Narcolepsy**

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

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

**B. Cataplexy with Narcolepsy**

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

1. The diagnosis of narcolepsy is confirmed by a sleep lab evaluation.
2. The member experiences at least 3 cataplexy attacks per week.[9]

**Continuation of Therapy:**

**A. Excessive Daytime Sleepiness 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.

**B. 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.

**Approval Duration and Quantity Restrictions:**

Approval: 12 months

Quantity Level Limit: 60 tablets every 30 days

**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 February 24, 2023.
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.