| Effective Date: 5/2020 |
| --- |
| Reviewed: 2/2020<br>Scope: Medicaid |

# SPECIALTY GUIDELINE MANAGEMENT

# WAKIX (pitolisant)

## POLICY

### I. 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
Wakix is indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.

All other indications are considered experimental/investigational and are not a covered benefit.

### II. PRESCRIBER SPECIALTIES

This medication must be prescribed by one of the following:

A. Sleep disorder specialist
B. Neurologist
C. Psychiatrist

### III. CRITERIA FOR INITIAL APPROVAL

**Narcolepsy**
Authorization of 6 months may be granted for treatment of excessive daytime sleepiness associated with narcolepsy in patients who are 18 years of age and older when all of the following criteria are met:

1. The patient has narcolepsy confirmed by sleep lab evaluation
2. The patient meets either of the following criteria:
    a. The patient has experienced an inadequate treatment response or intolerance to a central nervous system (CNS) stimulant drug (e.g., amphetamine/dextroamphetamine, methylphenidate)
    b. The patient has a clinical reason to avoid pharmacological treatment with a central nervous system (CNS) stimulant drug (e.g., substance use disorder), with rationale provided
3. The patient meets either of the following criteria:
    a. The patient experienced an inadequate treatment response to at least a one month trial of modafinil or armodafinil, unless intolerance experienced
    b. The patient has a clinical reason to avoid pharmacological treatment with modafinil and armodafinil (e.g., substance use disorder), with rationale provided

.

## IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continuation of Wakix when the patient has experienced a decrease in daytime sleepiness (documentation provided to support treatment efficacy).

## V. QUANTITY LIMIT

Wakix has a quantity limit of 2 tablets per day.

## VI. REFERENCES

1. Wakix [package insert]. Plymouth Meeting, PA: Harmony Biosciences, LLC; August 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed August 2019.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed August 2019.
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. Epstein LJ, Kristo D, Strollo PJ et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. J Clinical Sleep Medicine 2009:5(3):263-276.