Effective date: 5/1/2020
Reviewed: 2/2020, 2/2021, 11/2021, 2/2022, 4/2023, 3/2024, 4/2025 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

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

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

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by one of the following:

A. Sleep disorder specialist
B. Neurologist

III. CRITERIA FOR INITIAL APPROVAL

A. Member has one of the following:

a. Excessive Daytime Sleepiness with Narcolepsy

Authorization of 6 months may be granted for treatment of excessive daytime sleepiness (EDS) in patients 6 years of age and older with narcolepsy when all of the following criteria are met:

i. Documented diagnosis of narcolepsy is confirmed by a sleep lab evaluation
ii. Documentation that the member has experienced an inadequate treatment response, intolerance, or contraindication to a central nervous system (CNS) stimulant (i.e., amphetamine, dextroamphetamine, methylphenidate)
iii. If the member is 18 years of age or older: Documentation that the member has experienced an inadequate treatment response, intolerance to armodafinil or modafinil OR the member has a contraindication to both armodafinil and modafinil AND Documentation that the member has experienced an inadequate treatment response, intolerance or contraindication to Sunosi (solriamfetol)

b. Cataplexy with Narcolepsy

Authorization of 6 months may be granted for the treatment of cataplexy in adult patients with narcolepsy when all of the following criteria are met:

i. Documented Diagnosis of narcolepsy is confirmed by a sleep lab evaluation
ii. Documentation that the member has experienced an inadequate treatment response, intolerance, or contraindication to at least two of the following agents from a different drug class: atomoxetine, fluoxetine, clomipramine and/or venlafaxine

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment of adult and pediatric patients 6 years of age and older with excessive daytime sleepiness (EDS) with narcolepsy or cataplexy in adult patients with narcolepsy when the member has demonstrated and documented beneficial response to treatment with pitolisant therapy, defined as one of the following(documentation provided):

1. A reduction in symptoms of daytime sleepiness from baseline
2. Decrease in cataplexy episodes from baseline

V. QUANTITY LIMIT

Wakix 4.45mg & 17.8mg has a quantity limit of 2 tablets per day.

VI. REFERENCES

1. Wakix [package insert]. Plymouth Meeting, PA: Harmony Biosciences, LLC; June 2024.
2. Dauvilliers Y, Bassetti C, Lammers GJ, Arnulf I, Mayer G, Rodenbeck A, Lehert P, Ding CL, Lecomte JM, Schwartz JC; HARMONY I study group. 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 October 2020.