Reference number(s)
3176-A

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
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. CRITERIA FOR INITIAL APPROVAL

A. Excessive Daytime Sleepiness with Narcolepsy
Authorization of 12 months may be granted for treatment of excessive daytime sleepiness (EDS) in adult patients 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 has experienced an inadequate treatment response, intolerance or contraindication to a central nervous system (CNS) stimulant (i.e., amphetamine, dextroamphetamine, methylphenidate)
3. The member has experienced an inadequate treatment response, intolerance to armodafinil or modafinil OR the member has a contraindication to both armodafinil and modafinil

B. Cataplexy with Narcolepsy
Authorization of 12 months may be granted for the treatment of cataplexy in adult patients 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 experiences at least 3 cataplexy attacks per week

III. 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.

IV. REFERENCES

1. Wakix [package insert]. Plymouth Meeting, PA: Harmony Biosciences, LLC; October 2020.
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 March 2021.