

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Wakix (pitolisant)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Wakix (pitolisant)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Wakix (pitolisant) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Documentation is provided that individual is using to treat excessive daytime sleepiness associated with one of the following diagnoses:
 - A. Narcolepsy type 1 confirmed by the following (ICSD-3):
 1. Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least **one** of the following:
 - a. Clear cataplexy (defined as “more than one episode of generally brief [<2 min]) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness”); **AND**
 - b. Multiple Sleep Latency Test (MSLT) with **one** of the following:
 - i. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs); **OR**
 - ii. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG);
 - OR**
 - c. Cerebrospinal fluid hypocretin-1 deficiency (less than <100 pg/mL or less than one-third of the normative values with the same standardized assay);
 - OR**
 - B. Narcolepsy type 2 confirmed by the following (ICSD-3):
 1. Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months; **AND**
 2. Multiple sleep latency test (MSLT) with **one** of the following:

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- a. MSLT of less than 8 minutes and evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014); **OR**
- b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG); **AND**
3. The absence of cataplexy; **AND**
4. Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam, and PSG.

Requests for Wakix (pitolisant) may not be approved if the following criteria are met:

- I. Individual has severe hepatic impairment; **OR**
- II. Individual has a risk factor for prolonged QT interval; **OR**
- III. Individual is using with another drug that increases the QT interval.

Key References:

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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical Guideline for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults: Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med* 2009; 5(3):263-276. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699173/pdf/jcsm.5.3.263.pdf>. Accessed March 8, 2019.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
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7. Kapur VK, Auckley DH, Chowdhri S, et.al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: An American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2017; 13(3): 479-504. Available from: <https://aasm.org/resources/clinicalguidelines/diagnostic-testing-osa.pdf>. Accessed April 8, 2019.
8. Sateia MJ. International classification of sleep disorders – third edition: Highlights and modifications. *Chest*. 2014 Nov; 146(5): 1387-1394.
9. Szakacs Z, Dauvilliers Y, Mikhaylov V et al. Safety and efficacy of pitolisant on cataplexy in patients with narcolepsy: a randomized, double-blind, placebo-controlled trial. *Lancet*. 2017; 16: 200-7.
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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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