

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

## 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. 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

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New Program Date 10/08/2019

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.  
CRX-ALL-0448-19

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- occurring for at least 3 months; **AND**
2. Multiple sleep latency test (MSLT) with **one** of the following:
    - 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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: February 2, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.

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