Generic Name: Pitolisant

Applicable Drugs: Wakix®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/19/2022

Date Last Reviewed / Revised: 6/24/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI are met)

I. Documented diagnosis of one of the following conditions A or B and must meet criteria listed under applicable diagnosis:
   A. Cataplexy associated with narcolepsy
      1. Documented treatment failure with or contraindication to dextroamphetamine.
      2. Minimum age requirement: 18 years old.
   B. Excessive daytime sleepiness (EDS) associated with narcolepsy
      1. Documented treatment failure or contraindication to all the following a through c:
         a) Amphetamine, amphetamine-dextroamphetamine, or dextroamphetamine
         b) Modafinil or armodafinil
         c) Solriamfetol (Sunosi)
      2. Minimum age requirement: 6 years old.

II. Documentation of polysomnogram (PSG) and multiple sleep latency test (MSLT) confirming the diagnosis of narcolepsy (see Appendix Table 1).

III. Documentation of PSG (with at least 6 hours of sleep time) that shows the absence of other pathology which would cause chronic daytime sleepiness or documentation that known contributing pathology is adequately treated.

IV. Treatment is prescribed by or in consultation with a neurologist or sleep disorder specialist.

V. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VI. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- End-stage renal disease (ESRD).
- Severe hepatic impairment.

OTHER CRITERIA

- For patients with eGFR less than 60 mL/min/1.73 m^2, the maximum dosage is 17.8 mg once daily (quantity limit of 30 tablets per 30 days).
- For patients with moderate hepatic impairment (Child-Pugh Class B), the maximum dose is 17.8 mg once daily (quantity limit of 30 tablets per 30 days).
- For concomitant use with strong CYP2D6 inhibitors, the maximum dosage is 17.8 mg once daily for adults and pediatric patients weighing ≥40kg, or 8.9 mg for pediatric patients weighing <40 kg.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 60 tablets per 30 days

APPROVAL LENGTH

- **Authorization:** 4 months
- **Re-Authorization:** 1 year, with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

Table 1. Diagnostic criteria for narcolepsy

Narcolepsy type 1 (with cataplexy)
Criteria a and b must be met: a) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months. b) The presence of one or both of the following: o Cataplexy and a mean sleep latency of ≤8 minutes and ≥2 SOREMPs on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT. o CSF orexin-A concentration, measured by immunoreactivity, is either ≤110 pg/mL or <1/3 of mean values obtained in normal subjects with the same standardized assay.
Narcolepsy type 2
Criteria a through e must be met: a) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months. b) A mean sleep latency of ≤8 minutes and ≥2 SOREMPs are found on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT. c) Cataplexy is absent.

d) Either CSF orexin concentration has not been measured or CSF orexin concentration measured by immunoreactivity is either >110 pg/mL or >1/3 of mean values obtained in normal subjects with the same standardized assay.

e) The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal.

REFERENCES

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3. Scammell TE. Treatment of narcolepsy in adults. In: Benca R, ed. *UpToDate*. UpToDate; 2022. Accessed December 1, 2022. https://www.uptodate.com/contents/treatment-of-narcolepsy-in-adults#H2092033727
4. Wakix®. Prescribing information. Harmony Biosciences, LLC; 2022. Accessed February 2, 2024. https://www.wakixhcp.com/assets/pdf/WAKIX%20(pitolisant)%20tablets%20PI.pdf