

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 24, 2020 July 10, 2020, November 13, 2020, November 24, 2020, June 27, 2023

WAKIX[®] (pitolisant)

LENGTH OF AUTHORIZATION: One year

REVIEW CRITERIA:

- The patient must be 18 years of age or older; **AND**
- The medication must be prescribed by **or in consultation with** a sleep specialist or neurologist; **AND**
- The patient has a diagnosis of narcolepsy according to International Classification of Sleep Disorders (ICSD-3) or Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria; **AND**
- The patient has excessive daytime sleepiness associated with narcolepsy **OR** cataplexy with narcolepsy as confirmed by documented sleep testing (e.g. polysomnography, multiple sleep latency test); **AND**
- For the diagnosis of excessive daytime sleepiness associated with narcolepsy
 - Trial and failure of at least one CNS stimulant; **AND**
 - Trial and failure of modafinil.

CONTINUATION OF THERAPY

- Patient met initial review requirements; **AND**
- Clinical response to therapy submitted (supporting documentation required); **AND**
- **Patient has not experienced any treatment-restricting adverse effects; AND**
- **Dosing is appropriate as per labeling or is supported by compendia.**

DOSING AND ADMINISTRATION:

- **Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>**
- **Available as 4.45 mg and 17.8 mg tablet.**