Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 24, 2020 July 10, 2020, November 13, 2020, November 24, 2020

WAKIX® (pitolisant)

LENGTH OF AUTHORIZATION: ONE YEAR

REVIEW CRITERIA:

- The patient must be 18 years of age or older;
- The medication must be prescribed by a sleep specialist or neurologist
- 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);
- 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.
- Clinical response to therapy submitted (supporting documentation required).
- Dosage and administration does not exceed FDA approved maximum for the patient's indication.
- Supporting documentation required if dose requested exceeds FDA approved maximum

DOSING AND ADMINISTRATION:

The recommended dosage range is 17.8 mg to 35.6 mg daily.
Titrate dosage as follows: Starting dose is 8.9 mg by mouth once daily in the morning for one week; then 17.8 mg once daily in the morning for one week; then may increase to the maximum recommended dosage of 35.6 mg once daily in the morning.

Dosage Forms: Tablets: 4.45 mg and 17.8 mg