

Pitolisant (WAKIX)

Criteria for Use

May 2022

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTERnet](#) or [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to **ANY** item below is met, then the patient should **NOT** receive pitolisant.

- Excessive daytime sleepiness associated with OSA not receiving primary therapy (e.g., CPAP)
- Severe hepatic impairment (e.g., Child-Pugh C)
- Known hypersensitivity to pitolisant
- Receiving a drug known to prolong the QT interval
- End-stage renal disease (e.g., eGFR < 15 ml/min)
- Patient with known QT prolongation
- Symptomatic bradycardia
- Hypokalemia
- Hypomagnesemia
- Receiving a centrally acting histamine-1 receptor antagonist

Inclusion Criteria

The answers to **ALL** of the following must be fulfilled in order to meet criteria.

- Treatment of excessive daytime sleepiness (EDS) OR cataplexy associated with narcolepsy
- Epworth Sleepiness Scale (EES) is ≥ 14
- Documented lack of efficacy with, is intolerant of, or has contraindications to modafinil OR armodafinil
- Prescribed and monitored by a VA/VA Community Care sleep specialist / pulmonologist / neurologist or locally designated expert in sleep disorders

Prepared: May 2020. Updated November 2020, May 2022. Contact: Matthew A. Fuller, Pharm.D., BCPP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)