Wakix

I. Generic Name:
- a. Pitolisant

II. Brand Name:
- a. Wakix

III. Medication Class:
- a. Central nervous system stimulant; Histamine-3 receptor antagonist/inverse agonist

IV. FDA Approved Uses:
- a. Narcolepsy: To improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy

V. Application of Criteria:
- a. The following criteria apply to Illinois Medicaid, Michigan Medicaid, and Meridian Choice (HIX)

VI. Criteria for Use:
- a. Member must be 18 years of age or older
- b. Prescribed by a physician specializing in sleep medicine
- c. Patient must be clinically diagnosed with narcolepsy and have excessive daytime sleepiness that is substantial enough to warrant treatment
- d. Clinical documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months
- e. Exclusion of alternative causes of chronic daytime sleepiness (e.g. insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, idiopathic hypersomnia, effects of sedating medications)
- f. Documentation of compliance to non-pharmacologic interventions (e.g. napping/sleep hygiene, avoidance of medications that can worsen daytime sleepiness [benzodiazepines, opiates, antipsychotics, alcohol, theophylline, excessive caffeine])
- g. Current chart notes with plan of care recommending treatment with Wakix
- h. Documentation of adequate trial and failure and compliance to at least 3 months of treatment with each of the following:
    - A. Methylphenidate
    - B. Dextroamphetamine/amphetamine
    - C. Modafinil
    - D. Sunosi

Wakix

VII. Required Medical Information:

a. Proper diagnosis and documentation of an FDA approved indication
b. Current progress notes detailing the diagnosis with plan of care
c. Documentation of dose, date ranges of therapy, and clinical outcomes for all medications previously tried and failed
d. Complete chart notes documenting disease history
e. Polysomnography (PSG) consistent with narcolepsy ruling out other sleep disorders
f. Multiple sleep latency test (MSLT) documenting mean sleep latency of $\leq$ 8 minutes and two or more sleep onset REM periods (SOREMPs)
g. Baseline Epworth Sleepiness Scale (ESS) score
h. Documentation of CSF hypocretin concentration measured by immunoreactivity of either > 110 pg/mL or >1/3 of mean values obtained in normal subjects with the same standardized assay (Not required if lab work has not been performed)
i. Charts showing compliance to previous therapy and office visits

VIII. Contraindications:

a. Hypersensitivity to Pitolisant or any component of the formulation
b. Severe hepatic impairment

IX. Not Approved If:

a. Request is for Wakix as combination therapy used concurrently with either Sunosi or Xyrem
b. Patient shows non-compliance with previous treatment based on progress notes and/or pharmacy claims/fill history for required step therapies
c. Patient shows any contraindications to the use of Wakix as outlined in the FDA approved prescribing information
d. Request is for a non-FDA approved indication or dose

X. Length of Authorization:

a. Initial: 3 months
b. Continuation: up to 6 months

XI. Dosing:

a. Usual dosage: 17.8 to 35.6 mg once daily
b. Initial dosage: 8.9 mg once daily for 1 week
c. Dosage titration: Increase to 17.8 mg once daily for 1 week; in patients who are not CYP2D6 metabolizers, may further increase dose based on response and tolerability during week 3 to a maximum dose of 35.6 mg once daily

Wakix

XII. Criteria for Continuation of Therapy:

a. Initial therapy was tolerated
b. Demonstrated improvement in disease (improvement in the Epworth Sleepiness Scale score)
c. Patient must be compliant with taking the medication as prescribed
d. Patient must not be experiencing any severe adverse reaction while taking the medication
e. Office visit every 3-6 months with verified compliance and improvement or stability on drug

XII. Criteria for Discontinuation of Therapy:

a. Patient is non-compliant with pharmacologic or non-pharmacologic therapy
b. No demonstrable clinically significant improvement after initiation and stabilization of drug therapy
c. Patient is non-responsive to FDA-approved usual maximum dosing

XIII. References:

1. Pitolisant: Facts and Comparisons. Wolters Kluwer Health. May 2020
2. Wakix (pitolisant) Prescribing Information. Plymouth Meeting, PA; Harmony Biosciences LLC: August 2019.
3. Dauvilliers Y, Bassetti C, Lammers GJ, et al. Pitolisant versus placebo or modafinil in patients with narcolepsy: a double-blind, randomised trial. Lancet Neurol 2013; 12:1068.
4. Morgenthaler TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep 2007; 30:1705.
5. Scammell TE. The neurobiology, diagnosis, and treatment of narcolepsy. Ann Neurol 2003; 53:154.
6. Szakacs Z, Dauvilliers Y, Mikhaylov V, et al. Safety and efficacy of pitolisant on cataplexy in patients with narcolepsy: a randomised, double-blind, placebo-controlled trial. Lancet Neurol 2017; 16:200.

PHARMACY BENEFITS MANAGER

meridianRx

P.263 Approval Criteria

Wakix

Approved by: _____ Date: _____
CMO

Initial Approval:	
Revised:	
Annual Review:	
Next Review Date:	