

5.60.38

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Central Nervous System Drugs	Original Policy Date:	September 13, 2019
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Last Review Date: March 12, 2021

Wakix

Description

Wakix (pitolisant)

Background

Wakix (pitolisant) is a histamine-3 (H3) receptor antagonist/inverse agonist used for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy. Wakix's efficacy is thought to be mediated through its activity as an antagonist/inverse agonist at histamine-3 (H3) receptors (1).

Regulatory Status

FDA-approved indication: Wakix is indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy (1).

Wakix is contraindicated in patients with severe hepatic impairment. Wakix is extensively metabolized by the liver and there is significant increase in Wakix exposure in patients with moderate hepatic impairment (1).

Wakix contains a warning that it can prolong the QT interval. The use of Wakix should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval. Wakix should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes or sudden death, including symptomatic bradycardia, hypokalemia, or hypomagnesemia, and the presence of congenital prolongation of the QT interval. Patients with hepatic or renal impairment should be monitored for increased QTc (1).

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The safety and effectiveness of Wakix in pediatric patients less than 18 years of age have not been established (1).

Related Policies

Provigil-Nuvigil, Sunosi

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Wakix may be considered **medically necessary** in patients 18 years of age and older for the treatment of excessive daytime sleepiness or cataplexy with narcolepsy and if the conditions indicated below are met.

Wakix may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Excessive daytime sleepiness (EDS) due to narcolepsy
2. Cataplexy due to narcolepsy

AND ALL of the following:

- a. Inadequate treatment response, intolerance, or contraindication to **ALL** of the following:
 - i. Provigil (modafinil) or Nuvigil (armodafinil)
 - ii. Stimulant, such as amphetamine, methylphenidate, or dexamethylphenidate
- b. Patient has had a baseline evaluation of moderate to severe excessive sleepiness using **ONE** of the following sleep scales:
 - i. Epworth Sleepiness Scale (ESS)

(i.e.: <http://www.sleepapnea.org/wp-content/uploads/2017/02/ESS-PDF-1990->

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- 97.pdf)
 - ii. Multiple Sleep Latency Test (MSLT)
 - c. Prescriber agrees to monitor for QTc prolongation
 - d. **NO** severe hepatic impairment (Child-Pugh Class C)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Excessive daytime sleepiness (EDS) due to narcolepsy
2. Cataplexy due to narcolepsy

AND ALL of the following:

- a. Patient has had an improvement using **ONE** of the following sleep scales:
 - i. Epworth Sleepiness Scale (ESS)
(i.e.: <http://www.sleepapnea.org/wp-content/uploads/2017/02/ESS-PDF-1990-97.pdf>)
 - ii. Multiple Sleep Latency Test (MSLT)
- b. Prescriber agrees to monitor for QTc prolongation
- c. **NO** severe hepatic impairment (Child-Pugh Class C)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 180 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

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Rationale

Summary

Wakix (pitolisant) is a histamine-3 (H3) receptor antagonist/inverse agonist used for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy. Wakix's efficacy is thought to be mediated through its activity as an antagonist/inverse agonist at histamine-3 (H3) receptors. The safety and effectiveness of Wakix in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Wakix while maintaining optimal therapeutic outcomes.

References

1. Wakix [package insert]. Plymouth Meeting, PA: Harmony Biosciences, LLC; October 2020.

Policy History

Date	Action
September 2019	Addition to PA
December 2019	Annual review. Added "baseline evaluation of moderate to severe excessive sleepiness" per SME
October 2020	Addition of indication: cataplexy due to narcolepsy
December 2020	Annual review. Per FEP, revised initiation requirement to t/f Provigil or Nuvigil AND a stimulant
March 2021	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.