

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Wakefulness-Promoting Agents – Wakix Drug Quantity Management Policy – Per Rx

- Wakix® (pitolisant tablets – Harmony)

REVIEW DATE: 08/26/2022

OVERVIEW

Indication

Wakix, an antagonist/inverse agonist of the histamine-3 (H₃) receptor, is indicated for the following uses:¹

- **Excessive daytime sleepiness in adults with narcolepsy.**
- **Cataplexy in adults with narcolepsy.**

Dosing

The recommended dosage range for Wakix is 17.8 mg to 35.6 mg administered orally once daily (QD) in the morning upon waking.¹ Titrate dosage as follows:

- Week 1: Initiate with a dosage of 8.9 mg (two 4.45 mg tablets) QD;
 - Week 2: Increase dosage to 17.8 mg (one 17.8 mg tablet) QD;
 - Week 3: May increase to the maximum recommended dose of 35.6 mg (two 17.8 mg tablets) QD.
- Dose may be adjusted based on tolerability. If a dose is missed, patients should take the next dose the following day in the morning upon waking. It may take up to 8 weeks for some patients to achieve a clinical response. For patients with moderate hepatic impairment or with moderate-to-severe renal impairment, the maximum daily dose should not exceed 17.8 mg daily. Wakix is contraindicated in patients with severe hepatic disease and is not recommended in patients with end stage renal disease.

Availability

Wakix is available as 4.45 mg and 17.8 mg tablets supplied in bottles containing 30 tablets.¹

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Wakix. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted.

Automation: None.

Drug Quantity Limit

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Wakix® (pitolisant tablets)	4.45 mg tablets	30 tablets	90 tablets
	17.8 mg tablets	60 tablets	180 tablets

08/26/2022

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CRITERIA

Wakix 4.45 mg tablets

1. If the patient requires a daily dose of 8.9 mg, approve 60 tablets per dispensing at retail and 180 tablets per dispensing at home delivery.

Wakix 17.8 mg tablets

No overrides recommended.

REFERENCES

1. Wakix® tablets [prescribing information]. Plymouth Meeting, PA: Harmony Biosciences; March 2021.