BlueCross BlueShield
Federal Employee Program

WAKIX
(pitolisant)

RATIONALE FOR INCLUSION IN PA PROGRAM

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 a histamine-3 (H3) receptor antagonist/inverse agonist indicated for the: (1)

- treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy.
- treatment of excessive daytime sleepiness (EDS) in pediatric patients 6 years of age and older with narcolepsy.

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).

The safety and effectiveness of Wakix have not been established for treatment of EDS in pediatric patients less than 6 years of age with narcolepsy. The safety and effectiveness of Wakix have not been established for treatment of cataplexy in pediatric patients less than 18 years of age with narcolepsy (1).

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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, and for the treatment of EDS in pediatric patients 6 years of age and older with narcolepsy. Wakix's efficacy is thought to be mediated through its activity as an antagonist/inverse agonist at histamine-3 (H3) receptors (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; June 2024.