ALASKA MEDICAID
Prior Authorization Criteria

# Wakix®
# (pitolisant)

## FDA INDICATIONS AND USAGE[1]

Wakix® is a histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.

## APPROVAL CRITERIA[1,2,3,4,5]

1. Patient is 18 years of age or older **AND;**
2. Prescribed by or in consultation with a sleep specialist or neurologist **AND;**
3. Patient has a confirmed diagnosis of excessive daytime sleepiness (EDS) with narcolepsy indicated by **ALL** of the following:
    a. Baseline daytime sleepiness as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale);
    b. A mean sleep latency of ≤ 8 minutes AND ≥ 2 sleep onset REM periods (SOREMPs) are found on a mean sleep latency test (MSLT) performed according to standard techniques **AND;**
    c. Other causes for hypersomnolence such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal have been ruled out **AND;**
4. Patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for ≥ 3 months **AND;**
5. Patient has tried for a period of at least 30 days and failed at least one CNS stimulant drug (i.e. methylphenidate) or has a contraindication to stimulant use **AND;**
6. Patient has tried for a period of at least 30 days and failed at least one CNS promoting wakefulness drug (i.e. modafinil) or has a contraindication to use **AND;**
7. Sleep logs have been submitted for the last 30 days.

## DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR**;
2. Patient has severe hepatic impairment **OR**;
3. Patient has a history or risk factor for prolonged QT interval **OR**;
4. Patient is not and will no use drugs that prolong the QT interval **OR**;
5. Patient is using a histamine-1 (H1) receptor antagonist **OR**;
6. Patient is receiving treatment with sedative hypnotic agents (i.e. zolpidem, eszopiclone, zaleplon, benzodiazepines, barbiturates)

## CAUTIONS[1]

- Sensitive CYP3A4 Substrates (including hormonal contraceptives): WAKIX may reduce effectiveness of sensitive CYP3A4 substrates. Use an alternative non-hormonal contraceptive method during treatment with WAKIX and for at least 21 days after discontinuation of treatment.
- When used with strong CYP2D6 inhibitors, the maximum recommended dosage is 17.8 mg once daily.

**DURATION OF APPROVAL**

- Initial Approval: up to 3 months
- Re-authorization: up to 6 months with clinically meaningful chart notes showing the patient is responding positively to therapy.

**QUANTITY LIMITS**

- 53 -8.9mg tabs per 30 days
- 60 – 17.8mg tabs per 30 days

**REFERENCES / FOOTNOTES:**

1. Wakix [package insert]. Plymouth Meeting, PA; Harmony Biosciences; August 2019.
2. Nieto-Alamilla G, Márquez-Gómez R, García-Gálvez AM, et al. The Histamine H3 Receptor: Structure, Pharmacology, and Function. Mol Pharmacol. 2016; 90(5): 649-673.
3. Kapur VK, Auckley DH, Chowdhri S, et.al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: An American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017; 13(3): 479-504.
4. Szakacs Z, Dauvilliers Y, Mikhaylov V et al. Safety and efficacy of pitolisant on cataplexy in patients with narcolepsy: a randomized, double-blind, placebo-controlled trial. Lancet. 2017; 16: 200-7.
5. Dauvilliers Y, Bassetti C, Lammers GJ, Arnulf I, et al. Pitolisant vs placebo or modafanil in patients with narcolepsy: a double-blind, randomized trial. Lancet Neurol. 2013; 12: 1068-75.