

<b>Policy Name:</b>	<b>Wakix (pitolisant)</b>	<b>Policy #:</b>	<b>2765P</b>
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## Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Wakix (pitolisant).

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Wakix under the specialty pharmacy benefit if the following criteria have been met.

## Criteria

### 1. Coverage Criteria for Narcolepsy

- 1.1 Documented diagnosis of cataplexy or excessive daytime sleepiness with narcolepsy, confirmed by sleep lab evaluation
- 1.2 Ordered by a neurologist (nervous system doctor) or sleep specialist
- 1.3 Documented failure, intolerance, or contraindication to armodafinil or modafinil (adults only)
- 1.4 Documented failure, intolerance, or contraindication to Sunosi (adults only)

### 2. Approval Period

- 2.1 Initial: 12 months
- 2.2 Reauthorization: 12 months with documented clinical benefit

## CPT Codes

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## HCPCS Codes

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## References

1. Wakix (pitolisant) [prescribing information]. Plymouth Meeting, PA: Harmony Biosciences LLC; June 2024.
2. 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.
3. 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.
4. Maski K, Trotti L, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. *Journal of Clinical Sleep Medicine*, Vol. 17, No. 9: 1881-1893.

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This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.