Prior Authorization

The criteria to obtain coverage for initial treatment with WAKIX and reauthorizations for continued treatment will vary among insurance plans—after your office has submitted the WAKIX Prescription Referral Form, prior authorization (PA) may still be required. This guide provides information about criteria commonly required by insurance plans for PA and reauthorization.* **The healthcare provider office must complete and submit all PA requests and appeals directly to the insurance plan.**

*Coverage policies and criteria vary by insurance plan and are subject to change. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Harmony Biosciences cannot guarantee coverage or reimbursement.

Steps to help your patients access WAKIX

1 Verifying Eligibility

WAKIX is approved 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.

- Complete the WAKIX Prescription Referral Form and fax to ***WAKIX for You*** at 1-855-635-8520

Download the WAKIX Prescription Referral Form

2 Accessing WAKIX

- ***WAKIX for You*** can work with the insurance plan to determine coverage, and can help facilitate the approval process by providing necessary forms for completion
- Ensure PA criteria forms are fully filled out, if applicable
- If your office uses CoverMyMeds, ***WAKIX for You*** or the Specialty Pharmacy will initiate the prior authorization request in the CoverMyMeds platform†

†See back page for helpful information when using the CoverMyMeds platform for the PA process.

Exploring Financial Support

- ***WAKIX for You*** will assess patient eligibility for financial support programs, including copay support
- Eligible patients may pay as little as a **$0 copay on their WAKIX prescription**
  - This offer is only valid for patients with **commercial** (nongovernment-funded) insurance. Additional terms and conditions apply

Indications and Usage

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

Important Safety Information

Contraindications

- WAKIX is contraindicated in patients with known hypersensitivity to pitolisant or any component of the formulation. Anaphylaxis has been reported. WAKIX is also contraindicated in patients with severe hepatic impairment.

Prior Authorization (PA)

Common medical necessity criteria for initial approval (may not apply to all insurance plans)

G47.419 Narcolepsy without cataplexy (narcolepsy type 2)[1]

- ☑ Excessive daytime sleepiness (EDS) for ≥3 months[2,3]
- ☑ Multiple Sleep Latency Test (MSLT) and nocturnal polysomnography (PSG)[3,4]
- ☑ EDS and/or sleep laboratory test results are not better explained by other causes[2-4]
- ☑ Patient meets one of the following:
  - History of substance abuse[4-7]
  - Inadequate treatment response, intolerance, or contraindication to a central nervous system stimulant[5,7]
  - Inadequate treatment response, intolerance, or contraindication to armodafinil or modafinil[2,3,5-8]

G47.411 Narcolepsy with cataplexy (narcolepsy type 1)[1]

- ☑ Patient meets criteria for narcolepsy type 2 (see above)
- ☑ Patient has experienced cataplexy (>1 episode of sudden loss of muscle tone with retained consciousness)[3,4]
- ☑ Patient meets one of the following: inadequate treatment response, intolerance, or contraindication to plan-specified treatment(s) for EDS and/or cataplexy[2,3,5-8]

It is important to submit/upload the PA form PLUS additional documentation demonstrating the patient has met the insurance plan's medical necessity criteria (eg, sleep lab test results, symptom documentation, prior medications including dates and response, contraindications)

Medical necessity criteria vary by insurance plan and may change. Not all plans require the criteria listed, and some may require additional/different information. It is the provider's sole responsibility to confirm and refer to the criteria required by each patient's insurance plan.

Contact *WAKIX for You* with questions about the PA submission process.

1-855-WAKIX4U (1-855-925-4948)

Important Safety Information

Warnings and Precautions

- WAKIX prolongs the QT interval. Avoid use of WAKIX in patients with known QT prolongation or in combination with other drugs known to prolong the QT interval. Avoid use 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.
- The risk of QT prolongation may be greater in patients with hepatic or renal impairment due to higher concentrations of pitolisant; monitor these patients for increased QTc. Dosage modification is recommended in patients with moderate hepatic impairment and moderate or severe renal impairment. WAKIX is contraindicated in patients with severe hepatic impairment and not recommended in patients with end-stage renal disease (ESRD).

Wakix® pitolisant tablets

Prescriptions Including Both WAKIX Tablet Strengths May Require a PA for Each Strength

A PA may be required by both the primary and secondary insurance plans

Wakix pitolisant tablets

Reauthorization (Continuation of Therapy)

Common medical necessity criteria for reauthorization (may not apply to all insurance plans)

- ☑ Confirmation of diagnosis of narcolepsy type 1 (narcolepsy with cataplexy) or narcolepsy type 2 (narcolepsy without cataplexy)[3]
- ☑ Patient meets one or more of the following:
  - Previously approved for the requested agent through the plan's PA criteria[6]
  - No FDA-labeled contraindications to the requested agent[3,6]
  - Demonstrated clinical benefit with the requested agent (eg, reduction in EDS, decrease in cataplexy episodes)[3,4,6,8]

The Specialty Pharmacy will contact the HCP office when reauthorization is required. If you need to reach the Specialty Pharmacy, phone numbers are below.

Accredo By EVERNORTH	CVS specialty	PANTHERRX
1-800-987-4916	1-866-526-4151	1-866-797-4135

It is important to submit/upload documentation supporting beneficial response to therapy (eg, reduction in EDS, decrease in cataplexy episodes)

Important Safety Information

Adverse Reactions

- In the placebo-controlled clinical trials conducted in adult patients with narcolepsy with or without cataplexy, the most common adverse reactions (≥5% and at least twice placebo) for WAKIX were insomnia (6%), nausea (6%), and anxiety (5%). Other adverse reactions that occurred at ≥2% and more frequently than in patients treated with placebo included headache, upper respiratory tract infection, musculoskeletal pain, heart rate increased, hallucinations, irritability, abdominal pain, sleep disturbance, decreased appetite, cataplexy, dry mouth, and rash.
- In the placebo-controlled phase of the clinical trial conducted in pediatric patients 6 years and older with narcolepsy with or without cataplexy, the most common adverse reactions (≥5% and greater than placebo) for WAKIX were headache (19%) and insomnia (7%). The overall adverse reaction profile of WAKIX in the pediatric clinical trial was similar to that seen in the adult clinical trial program.

Drug Interactions

- Concomitant administration of WAKIX with strong CYP2D6 inhibitors increases pitolisant exposure by 2.2-fold. Reduce the dose of WAKIX by half.
- Concomitant use of WAKIX with strong CYP3A4 inducers decreases exposure of pitolisant by 50%. Dosage adjustments may be required.
- H_1 receptor antagonists that cross the blood-brain barrier may reduce the effectiveness of WAKIX. Patients should avoid centrally acting H_1 receptor antagonists.
- WAKIX is a borderline/weak inducer of CYP3A4. WAKIX may reduce the effectiveness of sensitive CYP3A4 substrates, including hormonal contraceptives. Patients using hormonal contraception should be advised to use an alternative non-hormonal contraceptive method during treatment with WAKIX and for at least 21 days after discontinuing treatment.

Helpful Tips

Wakix® pitolisant tablets

covermymeds®

If your office uses the CoverMyMeds platform:

- Some insurance plans require a PA for each WAKIX tablet strength prescribed, and a PA may be required for both the patient's primary and secondary insurance plans
  - Your office may receive unique key codes in separate communications (fax or email)
- **REMEMBER** to upload all supporting documentation
- If your office has questions, reach out to ***WAKIX for You*** or the Specialty Pharmacy, or use the CoverMyMeds chat function

It is important to fax a copy of PA requests, appeals, and all coverage decision letters (eg, approval, denial, additional information required) to *WAKIX for You*

Wakix for You™

Questions or updates?

Contact ***WAKIX for You***

1-855-WAKIX4U
(1-855-925-4948)
Monday–Friday, 8 AM–8 PM ET

1-855-635-8520

Important Safety Information

Use in Specific Populations

- There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are exposed to WAKIX during pregnancy. Patients should be encouraged to enroll in the WAKIX pregnancy registry if they become pregnant. To enroll or obtain information from the registry, patients can call 1-800-833-7460.
- The safety and effectiveness of WAKIX have not been established for the treatment of excessive daytime sleepiness in pediatric patients less than 6 years of age with narcolepsy. The safety and effectiveness of WAKIX have not been established for the treatment of cataplexy in pediatric patients with narcolepsy.
- WAKIX is extensively metabolized by the liver. WAKIX is contraindicated in patients with severe hepatic impairment. Dosage adjustment is recommended in patients with moderate hepatic impairment.
- WAKIX is not recommended in patients with end-stage renal disease. Dosage adjustment of WAKIX is recommended in patients with eGFR <60 mL/minute/1.73 m^2.
- Dosage reduction is recommended in patients known to be poor CYP2D6 metabolizers; these patients have higher concentrations of WAKIX than normal CYP2D6 metabolizers.

To report suspected adverse reactions, contact Harmony Biosciences at 1-800-833-7460 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References: 1. American Academy of Sleep Medicine. *International Classification of Sleep Disorders*. 3rd ed, text revision; 2023. **2.** OptumRx. Clinical criteria, step therapy, and quality limits for TennCare Preferred Drug List (PDL). Updated June 1, 2024. Accessed November 20, 2024. https://www.optumrx.com/content/dam/openenrollment/pdfs/Tenncare/home-page/preferred-drug-list/Criteria%20PDL.pdf **3.** CarelonRx. Approval criteria: WAKIX. Updated April 27, 2021. Accessed November 15, 2024. https://providers.anthem.com/docs/gpp/PHARM_ALL_Wakix.pdf?v=202106231816 **4.** UnitedHealthcare. Prior authorization/medical necessity: WAKIX (pitolisant). Updated January 1, 2024. Accessed November 20, 2024. https://www.uhcprovider.com/content/dam/provider/docs/public/prior-auth/drugs-pharmacy/commercial/r-z/PA-Med-Nec-Wakix.pdf **5.** Cigna Healthcare. Drug coverage policy: wakefulness-promoting agents - WAKIX. Updated November 1, 2024. Accessed November 20, 2024. https://static.cigna.com/assets/chcp/pdf/coveragePolicies/pharmacy/ip_0292_coveragepositioncriteria_pitolisant.pdf **6.** Prime Therapeutics. WAKIX (pitolisant) prior authorization with quantity limit: program summary. Updated April 1, 2024. Accessed November 20, 2024. https://www.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Boeing/Program_Summaries/Boeing_Wakix_PAQL_ProgSum.pdf. **7.** Express Scripts. Prior authorization with step therapy policy: wakefulness-promoting agents - WAKIX prior authorization with step therapy policy. Updated September 4, 2024. Accessed November 20, 2024. https://www.express-scripts.com/sites/default/files/policies/Wakefulness-Promoting%20Agents%20-%20Wakix%20PA%20with%20Step%20Therapy%20Policy_1.pdf **8.** Caremark. PA criteria. Updated November 1, 2024. Accessed November 20, 2024. https://www.caremark.com/portal/asset/FEP_MPDP_Criteria_Basic.pdf

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US-WAK-2400628/Jan 2025