Appeals

Denial of a prior authorization (PA) for WAKIX may be appealed in some instances. See the below tips on preparing and submitting an appeal to the insurance plan.* **The healthcare provider office must complete and submit 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.

Preparing and Submitting an Appeal

- ☑ Determine the deadline by which an appeal must be filed
  - The deadline to file the appeal should be in the denial letter
- ☑ Prepare the response using plan-specific medical necessity and PA criteria
  - Review the initial PA submission against the plan-specific criteria to verify that all supporting documentation was submitted/uploaded; include any missing documentation in the response
  - Determine and document the rationale for appeal
- ☑ Submit/upload all required documentation with the appeal submission, including:
  - Any required forms, including patient identification information
  - A copy of the denial or request for additional information
  - Supporting documentation demonstrating the patient has met the insurance plan's medical necessity criteria (eg, Letter of Medical Necessity [LMN], treatment history including dates and response, diagnostic test results, sleep laboratory testing reports)
  - Fax a copy of PA requests, appeals, and all coverage decision letters (approval, denial, additional information required) to ***WAKIX for You*** at 1-855-635-8520

Visit WAKIXRxCenter.com for downloadable resources to help complete a Letter of Medical Necessity, including an editable template.

Peer-to-Peer Review

Some insurance plans may offer peer-to-peer evaluation instead of submitting a formal appeal. If a PA was denied based on medical necessity, the HCP prescribing WAKIX may have the opportunity to discuss the need for treatment with a clinician who works for the insurance plan.

- ☑ Determine if the patient's insurance plan offers peer-to-peer review
- ☑ Submit the request for a peer-to-peer review to the insurance plan
- ☑ Ensure availability to participate in the peer-to-peer review within any time limits established by the insurance plan

Medical necessity criteria vary by insurance plan and may change. It is the provider's sole responsibility to confirm and refer to the criteria required by each patient's insurance plan.

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.

Notification of Appeal Decision

- The insurance plan will notify your office directly of their appeal decision; be sure to monitor your office fax for this notification
  - A decision regarding the appeal may take time, depending on the patient's plan
- If the denial of the PA is overturned, an explanation may be received and the claim processed
- If the denial of the PA is upheld, a denial letter may be received outlining any additional appeal rights

If your office is unsuccessful in obtaining approval from the patient's insurance plan, contact *WAKIX for You* to speak with a Patient Case Manager and ask whether your patient is eligible for other support programs.

REMINDER: It is important to fax a copy of PA requests, appeals, and all coverage decision letters (approval, denial, additional information required) to *WAKIX for You* at 1-855-635-8520

Important Safety Information

Warnings and Precautions

- WAKIX® (pitolisant) 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).

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.

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.

HARMONY BIOSCIENCES

Wakix® pitolisant tablets