**WAKIX® (pitolisant) Letter of Medical Necessity (LMN) Template**

Some payers may require prior authorization (PA) or additional supporting documentation to process and cover a claim for WAKIX. PA allows payers to review the rationale for the requested therapy and determine medical appropriateness. A patient-specific LMN will help to explain the healthcare provider’s clinical decision making in choosing a therapy.

Please see a general LMN template on the next page. This template contains bracketed fields for entering your patient’s medical history, demographic information, and rationale for treatment with WAKIX. You can fill in information by replacing bracketed fields with information specific to your patient and then print the letter on your office letterhead (if applicable). Please note that some prescriptions (such as concomitant use of WAKIX) may require additional or different content in the LMN, and some payers may have specific forms that must be completed to request PA or to document medical necessity.

**This letter template is for guidance only as an example of the information that may be required when submitting an LMN for WAKIX. It is the responsibility of the healthcare provider to customize the letter to reflect the unique background and to determine the correct diagnosis, treatment protocol, medical necessity, and content of LMN for each patient, as well as the requirements of the insurance plan involved. 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. Use of this LMN template does not guarantee coverage or reimbursement for WAKIX.**

**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**

WAKIX is contraindicated in patients with known hypersensitivity to pitolisant or any component of the formulation and in patients with severe hepatic impairment. WAKIX prolongs the QT interval. Avoid use of WAKIX with drugs that also increase QT and in patients with risk factors for prolonged QT interval. In placebo-controlled clinical trials in patients with narcolepsy, the most common adverse reactions (≥5% and at least twice placebo) for WAKIX in adult patients were insomnia, nausea, and anxiety; the most common adverse reactions (≥5% and greater than placebo) in pediatric patients 6 years and older were headache and insomnia.

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.

**Please see accompanying** [**Full Prescribing Information**](https://wakixhcp.com/pdf/wakix-tablets-pi.pdf)**.**

A logo with text and green and grey swirls

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[Note: This letter should be copied/printed on your office letterhead]

[Date]

|  |  |  |  |
| --- | --- | --- | --- |
| To: | [Contact Name] | RE: | [Patient Name] |
|  | [Insurance Company] |  | [Policy ID number] |
|  | [Address] |  | [Policy group] |
|  | [City, State ZIP] |  | [Patient date of birth]  [Patient diagnosis, ICD-10 code and description] |

Dear [Contact Name or Department]:

I am writing this letter to document the medical necessity for WAKIX® (pitolisant) for the treatment of [excessive daytime sleepiness; cataplexy] in my patient, [Patient Name], diagnosed with [diagnosis/ICD-10 code].

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. The Full Prescribing Information for WAKIX is enclosed.

In my clinical opinion, WAKIX is medically necessary for [Patient Name]. This letter outlines the patient's medical history and current condition, as well as the treatment rationale specifically related to the patient's diagnosis, [diagnosis/ICD-10 code].

1. Medical history, diagnosis, and current condition
   1. [Patient's diagnosis, condition, and medical history]
   2. [Previous therapies for the symptoms associated with the patient's diagnosis and the patient's response to previous therapies; if applicable, provide reasons for not prescribing another medication for the patient's condition (eg, contraindications)]
   3. [Brief description of the patient's recent symptoms and condition]
2. Rationale for treatment
   1. [Summary as to why, based on clinical judgment, the patient requires treatment with WAKIX]
   2. [Optional: Include additional justification (eg, WAKIX is non-scheduled; FDA-approved treatments for EDS in pediatric patients with narcolepsy are limited)]

Please contact my office at [phone number] if additional information is necessary. I look forward to receiving your timely response and approval.

Sincerely,

[Provider Signature]

[Provider Name], [Degree Initials]

NPI: [Provider identification number]

Enclosure(s):

Prescribing Information for WAKIX

[List additional enclosures as appropriate (eg, excerpts from patient medical records, clinical test results, prior authorization form, relevant clinical practice guidelines)]