

Letter of Medical Necessity Considerations for Nurtec[®] ODT (rimegepant)

Nurtec[®] ODT
(rimegepant)
orally disintegrating tablets 75 mg

A Letter of Medical Necessity can help support your rationale for treatment with Nurtec ODT. This letter explains why you feel that the prescribed product is medically necessary if your patient doesn't meet the health plan's full criteria for coverage. It can also accompany a prior authorization/reauthorization request or an appeal to reassess a denial. The information below may be considered by your office when drafting and submitting a Letter of Medical Necessity.



Letter of Medical Necessity Considerations

- ✓ If your patient's health plan has a coverage policy in place for the product, first review the policy to determine the criteria that your patient meets
- ✓ Confirm with the health plan if the letter should be addressed to a specific person or department
- ✓ Identify additional documents that may help support your rationale for prescribing the product. These may include:
 - Relevant patient medical records
 - Prescribing Information
 - FDA approval letter(s) (available on the FDA website)
 - Peer-reviewed literature (eg, treatment guidelines)
 - National Headache Foundation Position Statement
- ✓ Check if the health plan has its own request form for supporting medical necessity. If not, draft the letter on your practice's letterhead
- ✓ Specify if the product has been prescribed for acute treatment of migraine or preventive treatment of episodic migraine
- ✓ Clarify the requested quantity of the product if the prescribed amount differs from the plan's requirements
- ✓ Be clear about your patient's individual circumstances
- ✓ State why the preferred agents would not be appropriate therapies for your patient
- ✓ Describe your patient's condition with appropriate ICD-10-CM codes (eg, G43: Migraine, G43.0: Migraine without aura, G43.1: Migraine with aura, G43.9: Migraine, unspecified),^{1,*} including number of migraine/headache days per month, existing comorbidities, and allergies
- ✓ Submit the letter and documentation using the method preferred by the health plan (eg, fax, online portal)

FDA, US Food and Drug Administration; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; ODT, orally disintegrating tablet.

*This information is intended for informational purposes only and is not a comprehensive description of potential coding requirements for Nurtec ODT. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and accurate and appropriate coding for treatment of their patients. The information provided in this section should not be considered a guarantee of coverage or reimbursement for Nurtec ODT. The codes shown above are only general suggestions and are not intended to encourage or suggest a use of any drug that is inconsistent with FDA-approved use.

INDICATIONS

Nurtec ODT is indicated in adults for the:

- acute treatment of migraine with or without aura
- preventive treatment of episodic migraine

IMPORTANT SAFETY INFORMATION

Contraindications: Hypersensitivity to Nurtec ODT or any of its components.

Warnings and Precautions: If a serious hypersensitivity reaction occurs, discontinue Nurtec ODT and initiate appropriate therapy. Serious hypersensitivity reactions have included dyspnea and rash and can occur days after administration.

Adverse Reactions: The most common adverse reactions were nausea (2.7% in patients who received Nurtec ODT compared to 0.8% in patients who received placebo) and abdominal pain/dyspepsia (2.4% in patients who received Nurtec ODT compared to 0.8% in patients who received placebo). Hypersensitivity, including dyspnea and rash, occurred in less than 1% of patients treated with Nurtec ODT.

Please see next page for additional Important Safety Information and accompanying full Prescribing Information.

Sample Letter of Medical Necessity

The information below may be helpful when drafting a letter of medical necessity.

Sample Letter of Medical Necessity

Date of request: [Date]

ATTN:
[Contact name]
[Health plan name]
[Health plan address]
[City, State ZIP Code]
[Fax number]

RE: Letter of Medical Necessity for [Product name]
[Insured Patient First Name Patient Last Name]
Date of birth: [Month Day, Year]
[Policy #][Group #]

To whom it may concern:

My name is [Provider First Name Provider Last Name, medical specialty (National Provider Identifier number)], and I am writing on behalf of [Patient First Name Patient Last Name] to request approval to treat [Patient name] with [Product name]. [Patient name] has been in my care since [Month Day, Year], for the [FDA-approved indication].

Based on my clinical judgment, I believe that [Product name] is specifically medically necessary for [patient name] because [rationale for prescribing [Product name]].

Please promptly review the enclosed information in order to authorize treatment of [Product name] for [patient name]. My office can be contacted at [phone number] or [email address] if additional information is required to approve this request. Thank you in advance for your timely attention to this matter.

Sincerely,

[Physician name, medical specialty, National Provider Identifier number]
[Physician address]
Phone number: [Physician phone number] Fax number: [Physician fax number]

Enclosures [for consideration]:
[Relevant patient medical records]
[Prescribing Information]
[FDA Approval Letter(s)]
[Peer-reviewed literature (eg, treatment guidelines)]
[National Headache Foundation Position Statement]

Include additional details to help identify your patient, such as health plan policy and group numbers

State that you are writing on behalf of your patient to request approval of the product

Explain why the product is an appropriate treatment for your patient

Describe your patient's condition and list current and previous therapies (eg, triptans or oral prophylactic agents²), including dose, frequency, dates of use, reasons for discontinuation, and contraindications, if any

Provide your contact information in case the health plan needs more information to reassess coverage

List any additional documents that you have determined to include with the letter

IMPORTANT SAFETY INFORMATION (cont.)

Drug Interactions: Avoid concomitant administration of Nurtec ODT with strong inhibitors of CYP3A4, or strong or moderate inducers of CYP3A. Avoid another dose of Nurtec ODT within 48 hours when it is administered with moderate inhibitors of CYP3A4 or potent inhibitors of P-gp.

Use in Specific Populations: *Pregnancy:* It is not known if Nurtec ODT can harm an unborn baby. *Lactation:* The transfer of rimegepant into breastmilk is low (<1%). *Hepatic impairment:* Avoid use of Nurtec ODT in persons with severe hepatic impairment. *Renal impairment:* Avoid use in patients with end-stage renal disease.

Please see accompanying full Prescribing Information.

References: **1.** Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. <https://www.cms.gov/files/zip/2023-code-tables-tabular-and-index.zip>. Updated July 22, 2022. Accessed December 19, 2022. **2.** Cigna. Drug and biologic coverage policy: rimegepant. https://static.cigna.com/assets/chcp/pdf/coveragePolicies/pharmacy/ip_0147_coveragepositioncriteria_rimegepant.pdf. Published April 1, 2022. Accessed December 19, 2022.