PA Appeal Considerations for Nurtec® ODT (rimegepant)

Nurtec® ODT (rimegepant) orally disintegrating tablets 75 mg

If your patient's health plan denies coverage for Nurtec ODT, there may be an appeal process available. A Letter of Appeal allows you to further explain your clinical rationale for prescribing Nurtec ODT and request approval. The information below may be considered by your office staff as you draft and submit a Letter of Appeal. Check with your patient's health plan to confirm the time frame and specific process, as there may be varying levels of appeals.

Letter of Appeal Considerations

- If not stated in the denial communication, 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)
  - Letter of Medical Necessity
  - National Headache Foundation Position Statement
- Check if the health plan has its own request form for appeals. If not, draft the letter on your practice's letterhead
- Use exact language from the health plan's denial letter when explaining the reasons for denial
- Specify if the product has been prescribed for acute treatment of migraine or preventive treatment of episodic migraine
- 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 Appeal

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

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- Include additional details to help identify your patient, such as health plan policy and group numbers, diagnosis, claim number, and submission and denial dates
- State that you are writing on behalf of your patient to appeal the denial of coverage for 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 agents[2]), 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

Sample Letter of Appeal

Date of request: [Date]
[Request for Expedited Review]

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

RE: Appeal for Denial of [Product name]
[Insured Patient First Name Patient Last Name]
Date of birth: [Month Day, Year]
[Policy #][Group #]
Diagnosis: [ICD-10-CM Code][Diagnosis]
[Claim or Reference # (if known)]
Submission date: [Submission date] Denial date: [Denial date]

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 appeal the denial of coverage for [Product name]. [Patient name] has been in my care since [date] for the [FDA-approved indication].

In a letter dated [date of denial letter], coverage for [Product name] was denied due to [reason(s) for denial stated in denial letter]. I have reviewed your letter and, based on my medical expertise, believe that [Product name] is the appropriate treatment for [patient name] because [rationale for prescribing [Product name]].

Based upon my clinical judgment, I request that you consider approving [Product name] for my patient. I have enclosed additional documentation to further support medical necessity of [Product name] for [patient name]. My office can be contacted at [phone number] or [email address] if additional information is required to overturn this decision.

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]
[Letter of Medical Necessity]
[Prescribing Information]
[FDA Approval Letter(s)]
[Peer-reviewed literature (eg, treatment guidelines)]
[National Headache Foundation Position Statement]

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.

PP-NNT-USA-0207. January 2023.