# Letter of Medical Necessity Considerations for Nurtec<sup>®</sup> ODT (rimegepant)



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			
$\overline{\heartsuit}$	If your patient's health plan has a coverage policy in place for the product, first review the policy to determine the criteria that		Specify if the product has been prescribed for acute treatment of migraine or preventive treatment of episodic migraine	
$\overline{\heartsuit}$	your patient meets Confirm with the health plan if the letter should be addressed to a specific person or department	(	Clarify the requested quantity of the product if the prescribed amount differs from the plan's requirements	
$\heartsuit$	<ul> <li>Identify additional documents that may help support your rationale for prescribing the product. These may include:</li> <li>Relevant patient medical records</li> <li>Prescribing Information</li> <li>FDA approval letter(s) (available on the FDA website)</li> <li>Peer-reviewed literature (eg, treatment guidelines)</li> <li>National Headache Foundation Position Statement</li> </ul>		Be clear about your patient's individual circumstances State why the preferred agents would not be appropriate therapies for your patient	
		( N ( i	Describe your patient's condition with appropriate ICD-10-CM codes (eg, G43: Migraine, G43.00: Migraine without aura, not intractable, G43.01: Migraine without aura, intractable, G43.10: Migraine with aura, not intractable, G43.11: Migraine with aura, intractable, G43.90: Migraine, unspecified, not intractable)), <sup>1,*</sup> including number of migraine/headache days per month, existing comorbidities, and allergies	
$\heartsuit$	Check if the health plan has its own request form for supporting medical necessity. If not, draft the letter on your practice's letterhead		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**

**Hypersensitivity Reactions:** 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.

**Hypertension:** Development of hypertension and worsening of pre-existing hypertension have been reported following the use of CGRP antagonists, including Nurtec ODT, in the postmarketing setting.

Monitor patients for new-onset hypertension or worsening of pre-existing hypertension and consider whether discontinuation is warranted.

**Raynaud's Phenomenon:** Development of Raynaud's phenomenon and recurrence or worsening of pre-existing Raynaud's phenomenon have been reported in the postmarketing setting following the use of CGRP antagonists, including Nurtec ODT.

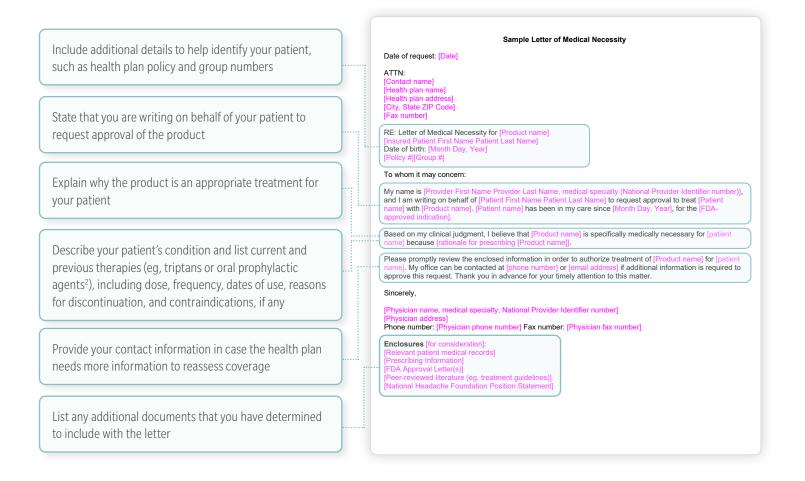
If signs or symptoms of Raynaud's phenomenon develop, discontinue Nurtec ODT. Patients should be evaluated by a healthcare provider if symptoms do not resolve. Patients with a history of Raynaud's phenomenon should be monitored for and informed about the possibility of worsening or recurrence of signs and symptoms.

### Please see next page for additional Important Safety Information and click <u>here</u> for full Prescribing Information.

# **Sample Letter of Medical Necessity**

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





#### **IMPORTANT SAFETY INFORMATION (cont.)**

**Adverse Reactions:** The most common adverse reactions for Nurtec ODT vs placebo were nausea (2.7% vs 0.8%) and abdominal pain/dyspepsia (2.4% vs 0.8%).

**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 breast milk 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 click here for 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/2025-code-tables-tabular-and-index-april.zip. Updated January 15, 2025. Accessed April 21, 2025. 2. Medical Mutual. Drug policy: Nurtec ODT (rimegepant). https://www.medmutual.com/-/media/MedMutual/Files/Providers/Prior-Auth-Rx/Nurtec-ODT.pdf. Updated January 16, 2025. Accessed April 21, 2025.

