MEDICAL MUTUAL®

Drug Policy

Policy:	Nurtec ODT (rimegepant)	Annual Review Date: 09/21/2023 Last Revised Date: 09/21/2023

OVERVIEW

Nurtec ODT is an oral calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine with or without aura in adults and preventive treatment of episodic migraine in adults.

POLICY STATEMENT

This policy involves the use of Nurtec ODT. Prior authorization is recommended for pharmacy benefit coverage of Nurtec ODT. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Nurtec ODT is recommended in those who meet the following criteria:

1. Acute Treatment of Migraine.

Criteria. *Patient must meet the following criteria (A, B, and C):*

- **A.** Patient has a diagnosis of migraine (See Appendix 1 below); AND
- **B.** The patient is 18 years or older; AND
- **C.** The patient meets one of the following criteria (i or ii):
  - i. The patient has tried at least one triptan therapy; OR
  - ii. The patient has a contraindication to triptan therapy according to the prescriber.

    Note: Examples of contraindications to triptans include a history of coronary artery disease; cardiac accessory conduction pathway disorders; history of stroke, transient ischemic attack, or hemiplegic or basilar migraine; peripheral vascular disease; ischemic bowel disease; uncontrolled hypertension; or severe hepatic impairment.

2. Preventive Treatment of Episodic Migraines in Adults

Criteria. *Patient must meet the following criteria (A, B, C, D, and E):*

A. Patient has a migraine diagnosis (See Appendix 1 below); AND
B. The patient is 18 years of age or older; AND
C. Patient has ≥ 4 and < 15 migraine headache days per month (prior to initiating a migraine-preventive medication); AND
D. Patient has tried at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class; AND

Note: Examples of standard prophylactic (preventive) pharmacologic therapies include angiotensin receptor blocker, anticonvulsant, beta-blocker, tricyclic antidepressant, other antidepressant, or Botox (Onabotulinumtoxin A).

E. Patient meets ONE of the following criteria (i, ii, or iii):
- **i.** Patient has had inadequate efficacy to both of those standard prophylactic (preventive) pharmacologic therapies, according to the prescriber; OR
- **ii.** Patient has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic (preventive) pharmacologic therapies, according to the prescriber; OR
- **iii.** Patient has had inadequate efficacy to one standard prophylactic (preventive) pharmacologic therapy and has experienced adverse event(s) severe enough to warrant discontinuation of another standard prophylactic (preventive) pharmacologic therapy, according to the prescriber.

3. **Continuation of therapy for acute or preventive treatment of migraine.** Approve if patient meets the following criteria (A, B, C, and D):

A. If the patient is currently taking a CGRP antagonist, the patient has had a significant clinical benefit from the medication as determined by the prescriber; AND

Note: Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that a CGRP antagonist was initiated.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 3 months (90 days)
B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Nurtec ODT has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Concomitant use with strong CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, clarithromycin)

2. Chronic cluster headaches

3. Hemiplegic migraines

4. Combination Therapy with Aimovig® (erenumab-aooe injection), Ajovy® (fremanezumab-vfrm injection), Emgality® (galcanezumab-gnlm injection), Vyepti® (eptinezumab-jjmr injection) or Qulipta (if Nurtec ODT is being taken for the preventive treatment of episodic migraine. Aimovig, Ajovy, Emgality, and Vyepti are injectable CGRP inhibitors for migraine prevention and have not been studied for use in combination with another agent in the same class. The clinical trial of Nurtec ODT for the preventive treatment of episodic migraine did not permit the use of a concomitant medication that acts on the CGRP pathway.

5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Olesen J, Bolay H, et al. The International Classification of Headache Disorders, 3rd edition. *Cephalagia*. 2018;38(1): 1-211.
2. Nurtec ODT [prescribing information]. New Haven, CT: Biohave Pharmaceuticals: May 2021.

Appendix 1

Migraine without aura	Migraine with aura
A. At least five attacks fulfilling criteria B–D B. Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated) C. Headache has at least two of the following four characteristics: 1. unilateral location	A. At least two attacks fulfilling criteria B and C B. One or more of the following fully reversible aura symptoms: 1. visual 2. sensory 3. speech and/or language 4. motor

2. pulsating quality 3. moderate or severe pain intensity 4. aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) D. During headache at least one of the following: 1. nausea and/or vomiting 2. photophobia and phonophobia E. Not better accounted for by another ICHD-3 diagnosis.	5. brainstem 6. retinal C. At least three of the following six characteristics: 1. at least one aura symptom spreads gradually over ≥5 minutes 2. two or more aura symptoms occur in succession 3. each individual aura symptom lasts 5-60 minutes 4. at least one aura symptom is unilateral 5. at least one aura symptom is positive 6. the aura is accompanied, or followed within 60 minutes, by headache D. Not better accounted for by another ICHD-3 diagnosis