PRIOR AUTHORIZATION POLICY

POLICY: Migraine – Nurtec ODT Prior Authorization Policy
- Nurtec® ODT (rimegepant sulfate orally disintegrating tablets – Biohaven)

REVIEW DATE: 02/15/2023; selected revision 08/02/2023

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Nurtec ODT, a calcitonin gene-related peptide (CGRP) receptor antagonist, is indicated in adults for the following uses:[1]
- **Acute treatment of migraine** with or without aura.
- **Preventive treatment of episodic migraine**.

Disease Overview

Migraine is a common, ongoing condition marked by paroxysmal, unilateral attacks of moderate to severe throbbing headache which is aggravated by routine physical activity (e.g., walking or climbing stairs) and associated with nausea, vomiting, and/or photophobia and phonophobia.[2] Migraines have been defined as chronic or episodic. Chronic migraine is described by the International Headache Society as headache occurring on ≥ 15 days/month for more than 3 months, which has the features of migraine headache on ≥ 8 days/month. Episodic migraine is characterized by headaches that occur < 15 days/month.

Guidelines

Triptans (e.g., almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, and zolmitriptan) are considered the gold standard for acute treatment of moderate to severe migraine headaches or mild to moderate migraine headaches

that respond poorly to over-the-counter analgesics.[2] An assessment of the preventive and acute treatment of migraine by the American Headache Society (2018; updated 2021) reaffirms previous migraine guidelines.[3,4] Nurtec ODT is not addressed for its preventive treatment of episodic migraine indication in the guideline. The update lists the triptans, dihydroergotamine, the oral gepants (Nurtec ODT and Ubrelvy® [ubrogepant tablets]), and Reyvow® (lasmiditan tablets) as effective treatments for moderate or severe acute migraine attacks and mild to moderate attacks that respond poorly to nonsteroidal anti-inflammatory drugs, non-opioid analgesics, acetaminophen, or caffeinated combinations (e.g., aspirin + acetaminophen + caffeine).

Patients with migraine should be considered for preventive treatment when attacks significantly interfere with patients' daily routines despite acute treatment; frequent attacks (≥ 4 monthly headache days); contraindication to, failure, overuse, or adverse events with acute treatments; or patient preference.[3,4] Before developing a preventive treatment plan, the appropriate use of acute treatments should be initiated and coupled with education and lifestyle modifications. All patients with migraine should be offered a trial of acute treatment. Based on the level of evidence for efficacy and the American Academy of Neurology scheme for classification of evidence, the following oral medications have established efficacy and should be offered for migraine prevention: antiepileptic drugs (**divalproex sodium, valproate sodium, topiramate** [not for women of childbearing potential without a reliable method of birth control]); beta-blockers (**metoprolol, propranolol, timolol**); and **frovatriptan** (for short-term preventive treatment of menstrual migraine). The following treatments are probably effective and should be considered for migraine prevention: antidepressants (**amitriptyline, venlafaxine**); beta-blockers (**atenolol, nadolol**); and angiotensin receptor blockers (**candesartan**). Additionally, the following treatments are possibly effective and can be considered for migraine prevention: calcium channel blockers (e.g., **verapamil**) and angiotensin converting enzyme inhibitors (e.g., **lisinopril**).[10,11]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Nurtec ODT. All approvals are provided for the duration noted below.

Nurtec® ODT (rimegepant sulfate orally disintegrating tablets – Biohaven) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Migraine, Acute Treatment.** Approve for 1 year if the patient meets the following (A and B):

A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
- **i.** Patient has tried at least one triptan therapy; OR
- **ii.** Patient has a contraindication to triptan(s) 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 Migraine. Approve for 1 year if the patient meets the following (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND
B) Patient has ≥ 4 and < 15 migraine headache days per month (prior to initiating a migraine-preventive medication); AND
C) Patient has tried at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class; AND
Note: Standard prophylactic (preventive) pharmacologic therapies include angiotensin receptor blocker, anticonvulsant, beta-blocker, tricyclic antidepressant, other antidepressant. A patient who has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine or Botox (onabotulinumtoxinA injection) for the prevention of migraine is not required to try two standard prophylactic pharmacologic therapies.
D) Patient meets ONE of the following (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; AND

E) If the patient is currently taking Nurtec ODT, patient has had a significant clinical benefit from the medication as determined by the prescriber.
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 Nurtec ODT was initiated.

CONDITIONS NOT COVERED

Nurtec® ODT (rimegepant sulfate orally disintegrating tablets – Biohaven) is(are) considered experimental, investigational, or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention if Nurtec ODT is being taken for the preventive treatment of episodic migraine.**
   Note: Examples of CGRP inhibitors that are indicated for migraine headache prevention include Aimovig (erenumab-aooe subcutaneous injection), Ajovy (fremanezumab-vfrm subcutaneous injection), Emgality (galcanezumab-gnlm subcutaneous injection), Vyepti (eptinezumab-jjmr intravenous infusion), Nurtec ODT (rimegepant sulfate orally disintegrating tablets), and Qulipta (atogepant tablets). 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.[5-8] Qulipta is an oral CGRP inhibitor for the preventive treatment of episodic migraine in adults.[9] The clinical trial of Nurtec ODT for the preventive treatment of episodic migraine did not allow the use of a concomitant medication that acts on the CGRP pathway.[1]

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

REFERENCES

1. Nurtec® ODT [prescribing information]. New Haven, CT: Biohaven; April 2022.
2. MacGregor EA. In the clinic. Migraine. *Ann Intern Med*. 2017;166(7):ITC49-ITC64.
3. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.
4. Ailani J, Burch RC, Robbins MS, on behalf of the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021;61(7):1021-1039.
5. Aimovig® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; October 2022.
6. Ajovy® subcutaneous injection [prescribing information]. North Wales, PA: Teva; September 2021.
7. Emgality® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; May 2022.
8. Vyepti® intravenous infusion [prescribing information]. Bothell, WA: Lundbeck; October 2022.
9. Qulipta™ tablets [prescribing information]. Madison, NJ: AbbVie; September 2021.
10. Micromedex. Merative LP. Available at: https://www.micromedexsolutions.com/. Accessed on August 7, 2023. Search terms: lisinopril, verapamil.
11. Clinical Pharmacology. ClinicalKey. Available at: https://www.clinicalkey.com/pharmacology/. Accessed on August 7, 2023. Search terms: lisinopril, verapamil.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/16/2022
Selected Revision	**Preventive Treatment of Episodic Migraine:** Criterion requiring a trial of a triptan in patients who are not currently taking Nurtec ODT was removed. **Conditions Not Covered :** • The criterion for combination use with Aimovig, Ajovy, Emgality, and Vyepti was changed to read "Concurrent use with another calcitonin	08/03/2022

	gene-related peptide (CGRP) inhibitor indicated for migraine headache prevention." • A Note was added to list the CGRP inhibitors that are indicated for migraine headache prevention, including Qulipta.	
Early Annual Revision	**Preventive Treatment of Episodic Migraine:** Angiotensin converting enzyme inhibitor and calcium channel blocker were removed from the Note listing examples of standard prophylactic (preventive) pharmacologic therapies.	02/15/2023
Selected Revision	**Preventive Treatment of Episodic Migraine:** The note with standard prophylactic (preventive) pharmacologic therapies was changed to remove "Examples of" and to include the statement: A patient who has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine or Botox (onabotulinumtoxinA injection) for the prevention of migraine is not required to try two standard prophylactic pharmacologic therapies.	08/02/2023