Drug Coverage Policy

Effective Date.....9/1/2025
Coverage Policy Number.....IP0147
Policy Title.....Nurtec ODT

Migraine – Nurtec ODT

- Nurtec® ODT (rimegepant sulfate orally disintegrating tablets – Biohaven)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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 (AHS) [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).

In the updated assessment by the AHS on the preventive and acute treatment of migraine, it states that patients with migraine should be considered for preventive treatment in the following situations: when attacks significantly interfere with patients' daily routines despite acute treatment; frequent attacks (≥ 4 monthly headache days); at least moderate disability (Migraine Disability Assessment [MIDAS] score ≥ 11 or six-item Headache Impact Test [HIT-6] score > 50); contraindication to, failure, overuse, or adverse events with acute treatments; or patient preference.[3,4] Before developing a preventive treatment plan, the appropriate use (e.g., drug type, route and timing of administration, frequency) 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 treatments have established efficacy and should be offered for migraine prevention: antiepileptic drugs (**divalproex sodium, valproate sodium, topiramate** [not for females 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**).

The **AHS** issued an update to their position statement (2024) specifically regarding therapies targeting CGRP for the prevention of migraine.[5] The evidence for the efficacy, tolerability, and safety of CGRP-targeting migraine preventive therapies (specifically, the monoclonal antibodies: Aimovig [erenumab-aooe subcutaneous {SC} injection], Ajovy® [fremanezumab-vfrm SC injection], Emgality® [galcanezumab-gnlm SC injection], and Vyepti® [eptinezumab-jjmr intravenous infusion] and the gepants: Nurtec® ODT and Qulipta® [atogepant tablets]) is substantial and consistent across different individual CGRP-targeting treatments. Extensive "real-world" clinical experience corroborates clinical trials. This data indicates that the efficacy and tolerability of CGRP-targeting therapies are equal to or greater than those of previous first-line therapies. The CGRP-targeting therapies should be considered as a first-line approach for migraine prevention along with previous first-line treatments without a requirement for prior failure of other classes of migraine preventive

treatment. Additionally, Botox® (onabotulinumtoxinA SC injection) is considered a first-line therapy for prevention of chronic migraine.

Coverage Policy

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

Nurtec ODT is considered medically necessary when ONE of the following is met:

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) Preferred product criteria are met for the product(s) as listed in the below table(s):

2. **Preventive Treatment of Episodic Migraine.** Approve for 1 year if the patient meets the following (A, B, C, and D):
   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) 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.
   D) Preferred product criteria are met for the product(s) as listed in the below table(s):

Employer Plans:

Product	Criteria
Nurtec ODT (rimegepant orally disintegrating tablets)	Migraine, Acute Treatment. Patient meets **ONE** of the following (1 or 2): 1. Patient meets one of the following (i or ii): i. Patient has tried one triptan products (for example, almotriptan [Axert, generics], eletriptan [Relpax, generics], frovatriptan [Frova, generics], naratriptan[Amerge, generics], rizatriptan [Maxalt, generics], sumatriptan [Imitrex, generics], zolmitriptan [Zomig, generics]); OR ii. Patient has tried one triptan/non-steroidal anti-inflammatory drug (NSAID) combination product (e.g., Treximet or Symbravo) [may require prior authorization] OR the patient has tried a triptan taken concomitantly with an NSAID; OR 2. Patient meets **ONE** of the following (i or ii): i. Per the prescriber, the patient has a contraindication to triptans; OR 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

Product	Criteria
	migraine; peripheral vascular disease; ischemic bowel disease; uncontrolled hypertension; or severe hepatic impairment. ii. Per the prescriber, the patient has had a significant intolerance to one or more triptans.

Individual and Family Plans:

Product	Criteria
Nurtec ODT (rimegepant orally disintegrating tablets)	Migraine, Acute Treatment. Patient meets **ONE** of the following (1 or 2): 1. Patient meets **ONE** of the following (i or ii): i. Patient has tried two triptan products (for example, almotriptan [Axert, generics], eletriptan [Relpax, generics], frovatriptan [Frova, generics], naratriptan [Amerge, generics], rizatriptan [Maxalt, generics], sumatriptan [Imitrex, generics], zolmitriptan [Zomig, generics]); OR ii. Patient has tried one triptan/non-steroidal anti-inflammatory drug (NSAID) combination product (e.g., Treximet or Symbravo) [may require prior authorization] OR the patient has tried a triptan taken concomitantly with an NSAID; OR 2. Patient meets **ONE** of the following (i or ii): i. Per the prescriber, the patient has a contraindication to triptans; OR 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. ii. Per the prescriber, the patient has had a significant intolerance to one or more triptans. Preventive Treatment of Episodic Migraine: Patient meets the following: 1. Patient has tried Emgality.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Nurtec ODT for any other use is considered not medically necessary, 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 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]

References

1. Nurtec® ODT [prescribing information]. New York, NY: Pfizer; April 2023.
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. Charles AC, Digre KB, Goadsby PJ, et al; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024;64(4):333-341.
6. Aimovig® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; October 2022.
7. Ajovy® subcutaneous injection [prescribing information]. North Wales, PA: Teva; September 2021.
8. Emgality® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; May 2022.
9. Vyepti® intravenous infusion [prescribing information]. Bothell, WA: Lundbeck; October 2022.
10. Qulipta® tablets [prescribing information]. Madison, NJ: AbbVie; April 2023.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Updated** coverage policy title from *Rimegepant* to *Migraine – Nurtec ODT.* **Migraine, Acute Treatment:** **Added** requirement for trial of two triptans for Individual and Family Plans.	6/1/2024

	Preventive Treatment of Episodic Migraine: **Removed** requirement for a *minimum 8-week trial* as it relates to migraine prevention therapies. **Added** preferred product criterion for Individual and Family Plans requiring failure, contraindication, or intolerance to Emgality.	
Selected Revision	**Migraine Headache Prevention:** The criteria requiring a patient to have tried at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class, and requiring that a patient has had inadequate efficacy or adverse event(s) severe enough to warrant discontinuation of those therapies have been removed.	7/15/2024
Annual Revision	**No criteria changes**	5/15/2025
Selected Revision	**Employer Plans and Individual and Family Plans Preferred Product Criteria Tables.** **Added** "The patient has tried and experienced inadequate efficacy or significant intolerance to one triptan/non-steroidal anti-inflammatory drug (NSAID) combination product OR the patient has tried and experienced inadequate efficacy or significant intolerance to a triptan taken concomitantly with an NSAID" exception criteria.	9/1/2025

The policy effective date is in force until updated or retired.