

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3145-10
Program	Step Therapy
Medication	Nurtec® ODT (rimegepant), Qulipta™ (atogepant), Ubrelvy™ (ubrogepant), Zavzpret™ (zavegepant)
P&T Approval Date	9/2020, 7/2021, 12/2021, 3/2022, 5/2022, 3/2023, 7/2023, 12/2023, 6/2024, 8/2024
Effective Date	10/15/2024

1. Background:

Nurtec ODT (rimegepant), Ubrelvy (ubrogepant) and Zavzpret (zavegepant) are calcitonin ene-related peptide receptor antagonists indicated for the acute treatment of migraine with or without aura in adults. Nurtec ODT is also indicated for the preventive treatment of episodic migraine in adults and Qulipta (atogepant) is indicated for the preventive treatment of migraine in adults.

The American Headache Society recommends the use of NSAIDs (including aspirin), non-opioid analgesics, acetaminophen, or caffeinated analgesic combinations (e.g., aspirin/acetaminophen/caffeine) for mild-to-moderate attacks and migraine-specific agents (i.e., triptans, dihydroergotamine [DHE]) for moderate or severe attacks and mild-to-moderate attacks that respond poorly to NSAIDs or caffeinated combinations.

Preventive treatment selection is based on evidence of efficacy, tolerability, patient preference, headache subtype, and comorbidities. The American Academy of Neurology guidelines note that antiepileptic drugs (divalproex sodium, valproate sodium, topiramate) and beta-blockers (metoprolol, propranolol, timolol) have established efficacy and that antidepressants (amitriptyline, venlafaxine) and beta-blockers (atenolol, nadolol) are probably effective for the preventive treatment of migraine headache.

This program requires a member to use lower cost options prior to receiving coverage for Nurtec ODT, Qulipta, Ubrelvy or Zavzpret.

2. Coverage Criteria^a:

A. Acute treatment of migraine

1. Nurtec ODT or **Ubrelvy** will be approved based on the following criterion:
 - a. History of a therapeutic failure (after at least 3 migraine episodes and a minimum of a 30-day trial) contraindication or intolerance to **two** of the following (document name and date tried):
 - 1) almotriptan (Axert)
 - 2) eletriptan (Relpax)
 - 3) frovatriptan (Frova)
 - 4) naratriptan (Amerge)

- 5) rizatriptan (Maxalt/Maxalt MLT)
- 6) sumatriptan (Imitrex)
- 7) zolmitriptan (Zomig/Zomig-ZMT)

Authorization will be issued for 12 months.

2. **Zavzpret** will be approved based on **both** of the following criterion:

a. - History of failure (after at least 3 migraine episodes and a minimum of a 30-day trial), contraindication, or intolerance to one of the following (Document duration of trial):

- 1) almotriptan (Axert®)
- 2) eletriptan (Relpax®)
- 3) frovatriptan (Frova®)
- 4) naratriptan (Amerge®)
- 5) rizatriptan (Maxalt®/Maxalt-MLT®)
- 6) sumatriptan (Imitrex®)
- 7) zolmitriptan (Zomig®)

-AND-

b. History of failure (after at least 3 migraine episodes and a minimum of a 30-day trial) contraindication or intolerance to **one** of the following (document drug and date tried):

- 1) sumatriptan (Imitrex) nasal spray
- 2) zolmitriptan (Zomig) nasal spray

Authorization will be issued for 12 months.

B. Prevention of Episodic Migraines

1. **Nurtec ODT** will be approved based on the following criterion:

a. History of failure (after a trial of at least two months^b), contraindication or intolerance to **two** of the following prophylactic therapies (document name and date tried):

- 1) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
- 2) Candesartan (Atacand)
- 3) Divalproex sodium (Depakote/Depakote ER)
- 4) a serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- 5) Topiramate (Topamax)
- 6) a tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

Authorization will be issued for 12 months.

C. Prevention of Migraines

1. **Qulipta** will be approved based on the following criterion:
 - a. History of failure (after a trial of at least two months^b), contraindication or intolerance to **two** of the following prophylactic therapies (document name and date tried):
 - 1) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
 - 2) Candesartan (Atacand)
 - 3) Divalproex sodium (Depakote/Depakote ER)
 - 4) OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
 - 5) a serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
 - 6) Topiramate (Topamax)
 - 7) a tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

Authorization will be issued for 12 months.

D. Other Diagnoses

1. Ubrelvy, Nurtec ODT, Qulipta or **Zavzpret** will be approved.

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

^b For Connecticut, Kentucky and Mississippi business, only a 30-day trial will be required.

3. Additional Clinical Programs:

- Supply limits may apply.
- Prior Authorization-Medical Necessity may apply
- Prior Authorization-Notification may apply
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Nurtec ODT [package insert]. New York, NY: Pfizer Inc; April 2023.
2. Qulipta [package insert]. North Chicago IL: AbbVie Inc; June 2023.
3. Ubrelvy [package insert]. North Chicago, IL: AbbVie; February 2023.
4. Zavzpret [package insert]. New York, Ny: Pfizer, Inc; March 2023.

5. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update AHS Consensus Statement. *Headache*. 2024; 64:333-41.
6. International Headache Society (IHS); Headache Classification Committee. The International Classification of Headache Disorders, 3rd edition. *Cephalalgia* 2018; 38:1-211.

Program	Step Therapy – Nurtec ODT, Qulipta, Ubrelvy, Zavzpret
Change Control	
Date	Change
9/2020	New program.
7/2021	Annual review. Added prevention of episodic migraines for Nurtec ODT. Updated the trial language to include 3 migraine episodes. Update references.
12/2021	Added Qulipta for preventive treatment of migraines. Updated references.
3/2022	Removed the step through the injectable CGRPs for Nurtec ODT. Added a step through Nurtec ODT for Qulipta. Updated the products typically excluded from coverage. Updated references.
5/2022	Updated state mandate language.
3/2023	Annual review. Added Zomig-ZMT as an example. Updated references.
7/2023	Added Zavzpret, updated Qulipta to trial and failure of two, updated references.
12/2023	Removed CGRP step and updated triptan step for Zavzpret. Condensed acute criteria for Nurtec ODT and Ubrelvy. Removed Zavzpret is typically excluded from coverage. Updated references.
6/2024	Removed notation that Qulipta is typically excluded from coverage. Removed CGRP step for Qulipta. Updated regulatory requirement. Updated references.
8/2024	Updated Zavzpret step and list of potential prophylactic therapies.