

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2023 P 2189-11
Program	Prior Authorization/Medical Necessity
Medication	Nurtec® ODT (rimegepant), Qulipta™ (atogepant)*, Ubrelvy™ (ubrogepant), Zavzpret™ (zavegepant)
P&T Approval Date	3/2020, 7/2020, 9/2020, 2/2021, 7/2021, 12/2021, 3/2022, 5/2022, 3/2023, 7/2023, 11/2023
Effective Date	3/1/2024

**1. Background:**

Nurtec ODT (rimegepant), Ubrelvy (ubrogepant) and Zavzpret (zavegepant) are calcitonin gene-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 try lower cost options prior to receiving coverage for Nurtec ODT, Qulipta\*, Ubrelvy or Zavzpret.

**2. Coverage Criteria<sup>a</sup>:**

**A. Initial Authorization**

1. **Ubrelvy** will be approved based on **all** of the following criteria:

a. Used for acute treatment of migraine

**-AND-**

b. History of 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)

-AND-

c. **One** of the following:

- 1) Patient is currently treated with one of the following prophylactic therapies:

- i) Amitriptyline (Elavil)
- ii) A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- iii) Candesartan (Atacand)
- iv) A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab)\*, Emgality (galcanezumab), Qulipta\*, Vyepti (eptinezumab-jjmr)^]
- v) Divalproex sodium (Depakote/Depakote ER)
- vi) OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- vii) Topiramate (Topamax)
- viii) Venlafaxine (Effexor/Effexor XR)

- OR -

- 2) Patient has < 4 migraine days per month

- OR -

- 3) Patient has  $\geq$  4 migraine days per month and has contraindication or intolerance to **one** of the following prophylactic therapies:

- i) Amitriptyline (Elavil)
- ii) A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- iii) Candesartan (Atacand)
- iv) A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab)\*, Emgality (galcanezumab), Qulipta\*, Vyepti (eptinezumab-jjmr)^]
- v) Divalproex sodium (Depakote/Depakote ER)
- vi) OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- vii) Topiramate (Topamax)
- viii) Venlafaxine (Effexor/Effexor XR)

-AND-

- d. Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonist (e.g., Nurtec ODT, Zavzpret)

**Authorization will be issued for 12 months.**

2. **Zavzpret** will be approved based on **all** of the following criteria:

- a. Used for acute treatment of migraine

-AND-

- b. **Both** of the following:

- 1) History of therapeutic failure (after at least 3 migraine episodes and a minimum of a 30-day trial), contraindication or intolerance to **both** of the following (document date tried):

- a) sumatriptan (Imitrex) nasal spray
- b) zolmitriptan (Zomig) nasal spray

-AND-

- 2) Provider attests that the patient is not a candidate for oral or sublingual CGRPs (e.g., nausea and/or vomiting, gastroparesis, inability to swallow pills)

-AND-

- c. **One** of the following:

- 1) Patient is currently treated with one of the following prophylactic therapies:

- a) Amitriptyline (Elavil)
- b) A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- c) Candesartan (Atacand)
- d) A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab)\*, Emgality (galcanezumab), Qulipta\*, Vypti (eptinezumab-jjmr)^]
- e) Divalproex sodium (Depakote/Depakote ER)
- f) OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- g) Topiramate (Topamax)
- h) Venlafaxine (Effexor/Effexor XR)

- OR -

- 2) Patient has < 4 migraine days per month

- OR -

- 3) Patient has  $\geq$  4 migraine days per month and has contraindication or intolerance to **one** of the following prophylactic therapies:
- a) Amitriptyline (Elavil)
  - b) A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
  - c) Candesartan (Atacand)
  - d) A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab)\*, Emgality (galcanezumab), Qulipta\*, Vyepti (eptinezumab-jjmr)^]
  - e) Divalproex sodium (Depakote/Depakote ER)
  - f) OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
  - g) Topiramate (Topamax)
  - h) Venlafaxine (Effexor/Effexor XR)

-AND-

- d. Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonist (e.g., Nurtec ODT, Ubrovelvy)

**Authorization will be issued for 12 months.**

3. **Nurtec ODT** will be approved based on **one** of the following criteria:

- a. **All** of the following:

- 1) Used for acute treatment of migraine

-AND-

- 2) 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):

- a) almotriptan (Axert)
- b) eletriptan (Relpax)
- c) frovatriptan (Frova)
- d) naratriptan (Amerge)
- e) rizatriptan (Maxalt/Maxalt MLT)
- f) sumatriptan (Imitrex)

g) zolmitriptan (Zomig/Zomig-ZMT)

**-AND-**

3) **One** of the following:

a) Patient is currently treated with one of the following prophylactic therapies:

- i) Amitriptyline (Elavil)
- ii) A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- iii) Candesartan (Atacand)
- iv) A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab)\*, Emgality (galcanezumab), Qulipta\*, Vyepti (eptinezumab-jjmr)^]
- v) Divalproex sodium (Depakote/Depakote ER)
- vi) OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- vii) Topiramate (Topamax)
- viii) Venlafaxine (Effexor/Effexor XR)

**-OR-**

b) Patient has < 4 migraine days per month

**-OR-**

c) Patient has  $\geq 4$  migraine days per month and has contraindication or intolerance to one of the following prophylactic therapies:

- i) Amitriptyline (Elavil)
- ii) A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- iii) Candesartan (Atacand)
- iv) A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab)\*, Emgality (galcanezumab), Qulipta\*, Vyepti (eptinezumab-jjmr)^]
- v) Divalproex sodium (Depakote/Depakote ER)
- vi) OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- vii) Topiramate (Topamax)
- viii) Venlafaxine (Effexor/Effexor XR)

**-AND-**

- 4) Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonists (e.g., Ubrelvy, Zavzpret)

**-OR-**

b. **All** of the following:

- 1) Diagnosis of episodic migraines with greater than or equal to 4 migraine days per month

**-AND-**

- 2) Used for preventive treatment of migraines

**-AND-**

- 3) History of failure (after a trial of at least two months<sup>b</sup>), contraindication or intolerance to **two** of the following prophylactic therapies (document name and date tried):

- a) Amitriptyline (Elavil)
- b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
- c) Candesartan (Atacand)
- d) Divalproex sodium (Depakote/Depakote ER)
- e) Topiramate (Topamax)
- f) Venlafaxine (Effexor/Effexor XR)

**-AND-**

- 4) Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g., Aimovig, Ajovy\*, Emgality, Qulipta\*, Vyepti^)

**Authorization will be issued for 12 months.**

4. Qulipta\* will be approved based on **all** of the following criteria:

- a. Diagnosis of migraine consistent with The International Classification of Headache Disorders, 3rd edition

**-AND-**

b. **One** of the following:

- 1) 4 to 7 migraine days per month and at least **one** of the following:

a) Less than 15 headache days per month

**-OR-**

b) Provider attests this is the member's predominant headache diagnosis (i.e., primary driver of headaches is not a different, non-migrainous condition)

**-OR-**

2) Greater than or equal to 8 migraine days per month

**-AND-**

c. Failure (after a trial of at least two months<sup>b</sup>), contraindication or intolerance to **two** of the following prophylactic therapies (document name and date tried):

- 1) Amitriptyline (Elavil)
- 2) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
- 3) Candesartan (Atacand)
- 4) Divalproex sodium (Depakote/Depakote ER)
- 5) OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- 6) Topiramate (Topamax)
- 7) Venlafaxine (Effexor/Effexor XR)

**-AND-**

d. Failure (after a trial of at least three months<sup>b</sup>), contraindication or intolerance to **two** of the following therapies used for the preventive treatment of migraines (document name and date tried):

- 1) Aimovig
- 2) Emgality (120 mg strength)
- 3) Nurtec ODT

**-AND-**

e. Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g., Aimovig, Ajovy\*, Emgality, Nurtec ODT, Vyepti^)

**Authorization will be issued for 12 months.**

## **B. Reauthorization**

1. **Ubrelvy or Zavzpret** will be approved based on **both** of the following criteria:

- a. Documentation of positive clinical response to therapy

-AND-

- b. Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonists (e.g., Nurtec ODT)

**Authorization will be issued for 12 months.**

2. Nurtec ODT will be approved based on **both** of the following criteria:

- a. Documentation of positive clinical response to therapy

-AND-

- b. **One** of the following:

- 1) **Both** of the following:

- a) Use is for the acute treatment of migraine

-AND-

- b) Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonist (e.g., Ubrovelvy, Zavzpret)

-OR-

- 2) **Both** of the following:

- a) Use is for the preventive treatment of migraines

- AND-

- b) Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g., Aimovig, Ajovy\*, Emgality, Qulipta\*, Vyepiti^)

**Authorization will be issued for 12 months.**

3. Qulipta\* will be approved based on **both** of the following criteria:

- a. Documentation of positive clinical response to therapy

-AND-

- b. Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g., Aimovig, Ajovy\*, Emgality, Nurtec ODT, Vyepiti^)



**Authorization will be issued for 12 months.**

<sup>a</sup> 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.

<sup>b</sup> For Connecticut business, only a 60-day trial will be required. For Kentucky and Mississippi business, only a 30-day trial will be required.

**\*Ajoy and Qulipta are typically excluded from coverage**

**^Vyepiti may be subject to additional benefit and coverage review requirements.**

### 3. Additional Clinical Programs:

- Supply limits 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]. Dublin, Ireland: Forest Laboratories Ireland, Ltd. June 2023.
3. Ubrelvy [package insert]. North Chicago, IL: AbbVie Inc: June 2023.
4. Zavzpret [package insert]. New York, NY: Pfizer Inc.; March 2023
5. The American Headache Society Position Statement on Integrating New Migraine Treatments Into Clinical Practice. AHS Consensus Statement. *Headache*. 2021; 61:1021-39.
6. International Headache Society (IHS); Headache Classification Committee. The International Classification of Headache Disorders, 3<sup>rd</sup> edition. *Cephalalgia* 2018; 38:1-211.

Program	Prior Authorization/Medical Necessity – Nurtec ODT, Ubrelvy, Zavzpret
<b>Change Control</b>	
Date	Change
3/2020	New program.
7/2020	Updated requirement from three triptans to two triptans. Modified concomitant CGRP language.
9/2020	Added a step requirement for Nurtec ODT through Ubrelvy. Noted that Nurtec ODT is typically excluded from coverage.
2/2021	Removed moderate to severe migraine requirement. Added requirement for < 4 migraines per month. Simplified criteria for >= 4 migraines per month. Added biologic CGRP to prophylactic therapies. Removed prescriber requirement from reauthorization.
7/2021	Added criteria for new preventive indication for episodic migraines for Nurtec ODT. Updated the trial language to include 3 migraine episodes. Added statement regarding concomitant therapy with other preventive CGRPs. Updated references.
12/2021	Added Qulipta for preventive treatment of migraines. Added candesartan as a preventive option. 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. Added note for Vyetpi regarding additional benefit and coverage review requirements. Updated references.
5/2022	Removed specialist requirement. Added Mississippi to state mandate language.
3/2023	Annual review. Added Zomig-ZMT as a zolmitriptan example. Added Qulipta as a prophylactic CGRP example and removed reference to biologic. Updated references.
7/2023	Added Zavzpret. Updated Qulipta criteria to allow both episodic and chronic migraines. Updated examples in prophylactic coverage. Included Botox as preventive option for Qulipta.
12/2023	Removed CGRP step, added a provider attestation and updated the triptan step for Zavzpret. Removed that Zavzpret is typically excluded from coverage. Updated references.