MEDICAL MUTUAL®

Drug Policy

Policy:	Qulipta (atogepant)	Annual Review Date: 09/21/2023 Last Revised Date: 09/21/2023

OVERVIEW

Qulipta is an oral calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of episodic migraine in adults.

POLICY STATEMENT

This policy involves the use of Qulipta. Prior authorization is recommended for pharmacy benefit coverage of Qulipta. 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 Qulipta is recommended in those who meet the following criteria:

1. **Preventive Treatment of Chronic Migraines in Adults**
   Criteria. *Patient must meet the following criteria (A, B, C, D, and E):*
   - **A.** Patient has a chronic migraine diagnosis according to the International Classification of Headache Disorders (ICHD-3) (See Appendix 1 below) [Documentation required]; AND
   - **B.** The patient is 18 years of age or older; AND
   - **C.** The patient has at least 15 headache days per month for greater than or equal to 3 months; AND
   - **D.** The provider has ruled out medication overuse as a possible cause of migraine; AND
   - **E.** Patient has tried at least two standard prophylactic pharmacologic therapies, each from a different pharmacologic class (at a maximum tolerated dose) each consisting of a 3-month trial unless an intolerance or contraindication exists [documentation required]: antidepressants such as amitriptyline or venlafaxine, beta blockers such as atenolol, metoprolol, nadolol, timolol, propranolol, or other medication such as divalproex sodium, topiramate or Botox.

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 according to the International Classification of Headache Disorders (ICHD-3) (See Appendix 1 below) [Documentation required]; AND
B. The patient is 18 years of age or older; AND
C. The patient has at least 3 headache days per month requiring bed rest or classified as severe impairment OR four headache days with at least some impairment; AND
D. The provider has ruled out medication overuse as a possible cause of migraine; AND
E. Patient has tried at least two standard prophylactic pharmacologic therapies, each from a different pharmacologic class (at a maximum tolerated dose) each consisting of a 3-month trial unless an intolerance or contraindication exists [documentation required]: antidepressants such as amitriptyline or venlafaxine, beta blockers such as atenolol, metoprolol, nadolol, timolol, propranolol, or other medication such as divalproex sodium or topiramate.

3. **Continuation of therapy for preventive treatment of Episodic Migraine** Approve if patient meets the following criteria (A and B):
   A. Patient is > 18 years of age; AND
   B. 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. [documentation required].

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

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Qulipta 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. Chronic cluster headaches

2. Concurrent Use with Another Calcitonin Gene-Related Peptide (CGRP) Inhibitor Being Prescribed for Migraine Headache Prevention.

   Note: CGRP inhibitors that are indicated for migraine headache prevention include 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] Nurtec ODT is an oral CGRP inhibitor indicated for the acute treatment of migraine and for preventive treatment of

episodic migraine.[9] Clinical trials of Nurtec ODT for the prevention of episodic migraine did not permit the use of a concomitant medication that acts on the CGRP pathway.

3. Hemiplegic migraines

4. 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. Qulipta [prescribing information]. Dublin, Ireland: Allergan Pharmaceuticals; October 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 2. pulsating quality 3. moderate or severe pain intensity 4. aggravation by or causing avoidance of	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 5. brainstem 6. retinal C. At least three of the following six characteristics:

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.	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