VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Migraine – Qulipta Prior Authorization Policy
- Qulipta™ (atogepant tablets – AbbVie)

REVIEW DATE: 02/15/2023; selected revision 05/03/2023

OVERVIEW

Qulipta, a calcitonin gene-related peptide (CGRP) receptor antagonist, is indicated for the **preventive treatment of migraine** in adults.[1]

Disease Overview

Migraine is a common, ongoing condition marked by paroxysmal, unilateral attacks of moderate to severe throbbing headache.[2] Migraines are aggravated by routine physical activity (e.g., walking or climbing stairs) and associated with nausea, vomiting, and/or photophobia and phonophobia. 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

An assessment of the preventive and acute treatment of migraine by the American Headache Society (2018; updated 2021) reaffirms previous migraine guidelines.[3,4] 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. 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. 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 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).

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Qulipta is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Preventive Treatment of Migraine.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has ≥ 4 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: Examples of standard prophylactic (preventive) pharmacologic therapies include angiotensin receptor blocker, anticonvulsant, beta-blocker, tricyclic antidepressant, other antidepressant.
   - **D)** Patient meets ONE of the following criteria (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 Qulipta, 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 Qulipta was initiated.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Qulipta is not recommended in the following situations:

1. **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 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] 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.

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. Qulipta™ tablets [prescribing information]. Madison, NJ: AbbVie; March 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. 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 injection [prescribing information]. Bothell, WA: Lundbeck; October 2022.
9. Nurtec® ODT orally disintegrating tablets [prescribing information]. New Haven, CT: Biohaven; April 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Selected Revision	**Preventive Treatment of Episodic Migraine:** Criterion requiring a trial of a triptan in patients who are not currently taking Qulipta was removed. **Conditions Not Recommended for Approval:** The criterion for combination use with Aimovig, Ajovy, Emgality, and Vyepti was changed to read "Concurrent use with another calcitonin 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.	08/03/2022
Annual Revision	No criteria changes.	10/12/2022
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 Migraine:** Qulipta is now indicated for both episodic and chronic migraine prevention. Therefore, "episodic" was removed from the approval condition. The criterion requiring the patient to have ≥ 4 and < 15 migraine headache days per month (prior to initiating a migraine-preventive medication) was changed to ≥ 4 migraine headache days per month (prior to initiating a migraine-preventive medication).	05/03/2023