VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 10/06/2021

OVERVIEW

Qulipta, a calcitonin gene-related peptide (CGRP) receptor antagonist, is indicated for the **preventive treatment of episodic 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

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 updated assessment of the **preventive and acute treatment of migraine by the American Headache Society** (2018) lists the triptans and dihydroergotamine as effective treatments for moderate or severe acute migraine attacks and mild to moderate attacks that respond poorly to nonsteroidal anti-inflammatory drugs (NSAIDs) or caffeinated combinations (e.g., aspirin + acetaminophen + caffeine).[3] Treat at the first sign of pain to improve the probability of achieving freedom from pain and reduce attack-related disability. 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. 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 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 Episodic Migraine.** Approve Qulipta 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 and < 15 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, angiotensin converting enzyme inhibitor, anticonvulsant, beta-blocker, calcium channel 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)** Patient meets ONE of the following (i or ii):
     - **i.** Patient is NOT taking Qulipta and meets ONE of the following (a or b):
       - **a)** Patient has tried at least one triptan therapy; OR
       - **b)** Patient has a contraindication to triptan(s) according to the prescriber; 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.** Patient is currently taking Qulipta and 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. **Combination Therapy with Aimovig (erenumab-aooe injection), Ajovy (fremanezumab-vfrm injection), Emgality (galcanezumab-gnlm injection), Vyepti (eptinezumab-jjmr injection), or Nurtec ODT (rimegepant orally disintegrating tablets) if Nurtec ODT is being taken for the**

preventive treatment of episodic migraine. Aimovig, Ajovy, Emgality, and Vyepti are injectable calcitonin gene-related peptide (CGRP) inhibitors for migraine prevention and have not been studied for use in combination with another agent in the same class.[4-7] Nurtec ODT is an oral CGRP inhibitor indicated for the acute treatment of migraine and for preventive treatment of episodic migraine.[8] 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; September 2021.
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. Aimovig® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; May 2021.
5. Ajovy® subcutaneous injection [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA; January 2020.
6. Emgality® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly and Company; December 2019.
7. Vyepti™ intravenous injection [prescribing information]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals; February 2020.
8. Nurtec™ ODT orally disintegrating tablets [prescribing information]. New Haven, CT: Biohaven Pharmaceuticals; May 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	10/06/2021