Effective Date **9/1/2023**
Next Review Date… **9/1/2024**
Coverage Policy Number **IP0377**

Atogepant

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Related Coverage Resources

Quantity Limitations - (1201)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for atogepant (**Qulipta**™).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Atogepant (Qulipta) is considered medically necessary when the following are met:

Preventive Treatment of Migraine. Individual meets **ALL** of the following criteria:

A. Age 18 years or older
B. 4 or more migraine headache days per month (prior to initiating Qulipta)
C. Documentation of **ONE** of the following:
    i. Failure following a minimum 8 week trial of **TWO** migraine prevention therapies from different classes of medications including the following:

a. Angiotensin receptor blockers or angiotensin-converting enzyme inhibitors
b. Antidepressants
c. Antiepileptic drugs
d. Beta-blockers

ii. Contraindication or intolerance to **ALL** of the following: angiotensin receptor blockers/angiotensin-converting enzyme inhibitors, antidepressants, antiepileptic drugs, and beta-blockers

iii. Failure, contraindication, or intolerance to a minimum 6 month trial of onabotulinumtoxinA (Botox) for chronic migraine prevention [requires prior authorization]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of atogepant (Qulipta) is considered medically necessary for preventive treatment of migraine when initial criteria are met AND beneficial response is demonstrated (for example, reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month).

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

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

Background

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); candesartan; 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); angiotensin-converting enzyme inhibitors (lisinopril) and angiotensin receptor blockers (candesartan) .

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; September 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; September 2021.
9. Nurtec® ODT orally disintegrating tablets [prescribing information]. New Haven, CT: Biohaven; April 2022.