PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 02/26/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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 updated assessment of the **preventive and acute treatment of migraine** by the **American Headache Society** (AHS) [2018; update 2021] reaffirms previous migraine guidelines.[3,4] Patients with migraine should be considered for preventive treatment in the following situations: when attacks significantly interfere with patients' daily routines despite acute treatment; frequent attacks (≥ 4 monthly

headache days); at least moderate disability (Migraine Disability Assessment [MIDAS] score ≥ 11 or six-item Headache Impact Test [HIT-6] score > 50); 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 females 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**).

The **AHS** issued an update to their position statement (2024) specifically regarding therapies targeting CGRP for the prevention of migraine.[5] The evidence for the efficacy, tolerability, and safety of CGRP-targeting migraine preventive therapies (specifically, the monoclonal antibodies: Aimovig [erenumab-aooe subcutaneous {SC} injection], Ajovy® [fremanezumab-vfrm SC injection], Emgality® [galcanezumab-gnlm SC injection], and Vyepti® [eptinezumab-jjmr intravenous infusion], and the gepants: Nurtec® ODT [rimegepant orally disintegrating tablets] and Qulipta is substantial and consistent across different individual CGRP-targeting treatments. Extensive "real-world" clinical experience corroborates clinical trials. This data indicates that the efficacy and tolerability of CGRP-targeting therapies are equal to or greater than those of previous first-line therapies. The CGRP-targeting therapies should be considered as a first-line approach for migraine prevention along with previous first-line treatments without a requirement for prior failure of other classes of migraine preventive treatment. Additionally, Botox® (onabotulinumtoxinA SC injection) is considered a first-line therapy for prevention of chronic migraine.

POLICY STATEMENT

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

- **Qulipta® (atogepant tablets – AbbVie)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Migraine Headache Prevention.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   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) 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 COVERED

- **Qulipta® (atogepant tablets – AbbVie)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.[6-9] Nurtec ODT is an oral CGRP inhibitor indicated for the acute treatment of migraine and for preventive treatment of episodic migraine.[10] 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.

REFERENCES

1. Qulipta® tablets [prescribing information]. Madison, NJ: AbbVie; April 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. Charles AC, Digre KB, Goadsby PJ, et al; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024;64(4):333-341.
6. Aimovig® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; October 2022.
7. Ajovy® subcutaneous injection [prescribing information]. North Wales, PA: Teva; September 2021.
8. Emgality® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; May 2022.
9. Vyepti® intravenous injection [prescribing information]. Bothell, WA: Lundbeck; October 2022.
10. Nurtec® ODT orally disintegrating tablets [prescribing information]. New York, NY: Pfizer; April 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
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
Selected Revision	**Migraine Headache Prevention:** Approval indication was changed from Preventive Treatment of Migraine to Migraine Headache Prevention. The note with standard prophylactic (preventive) pharmacologic therapies was changed to remove "Examples of" and expanded to include the statement: A patient who has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine or Botox (onabotulinumtoxinA injection) for the prevention of migraine is not required to try two standard prophylactic pharmacologic therapies.	08/02/2023
Annual Revision	No criteria changes.	02/28/2024
Selected Revision	**Migraine Headache Prevention:** The criteria requiring a patient to have tried at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class, and requiring that a patient has had inadequate efficacy or adverse event(s) severe enough to warrant discontinuation of those therapies have been removed.	04/10/2024
Annual Revision	No criteria changes.	02/26/2025