Clinical Policy: Atogepant (Qulipta)

Reference Number: AZ.CP.PHAR.566
Effective Date: 02.01.22
Last Review Date: 02.22
Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Atogepant (Qulipta™) is a calcitonin gene-related peptide receptor (CGRP) antagonist.

FDA approved indications

Qulipta™ is indicated for the preventative treatment of episodic migraine in adults.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Arizona Complete Health-Complete Care Plan and Care1st that Qulipta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Migraine Prophylaxis (must meet all)**:**

1. Diagnosis of episodic migraine;
2. Member experiences ≥ 4 migraine days per month for at least 3 months;
3. Member does not have chronic migraine, defined as ≥ 15 headache days/month with ≥ 8 migraine days/month for at least 3 months;
4. Prescribed by or in consultation with a neurologist, headache, or pain specialist;
5. Age ≥ 18 years;
6. Failure of at least TWO of the following oral migraine preventative therapies, each for 8 weeks and from different therapeutic classes, unless clinically significant adverse effects are experienced or all are contraindicated: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine);
7. Failure of 3-month trials of TWO CGRP inhibitors* (e.g., Aimovig®, Ajovy®, Emgality®) used for migraine prophylaxis, unless clinically significant adverse effects are experienced or all are contraindicated (see Appendix B);
   **Prior authorization may be required*.
8. Qulipta is not prescribed concurrently with Botox® or other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality, Nurtec ODT, Ubrelvy, Vyepti);
9. Dose does not exceed 60 mg per day.

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona Medicaid.

II. Continued Therapy

A. Migraine Prophylaxis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member has experienced and maintained positive response to therapy as evidenced by a reduction in migraine days per month from baseline;
3. Qulipta is not prescribed concurrently with Botox® or other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality, Nurtec ODT, Ubrelvy, Vyepti);
4. If request is for a dose increase, new dose does not exceed 60 mg per day.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – AZ.CP.PMN.53 for Arizona Medicaid.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AAN: American Academy of Neurology
AHS: American Headache Society
CGRP: Calcitonin gene-related peptide
FDA: Food and Drug Administration
MHD: Monthly Headache Day
MMD: Monthly Migraine Days

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Anticonvulsants such as: divalproex (Depakote®), topiramate (Topamax®), valproate sodium	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*
Beta-blockers such as: propranolol (Inderal®), metoprolol (Lopressor®)*, timolol, atenolol (Tenormin®)*, nadolol (Corgard®)*	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*
Antidepressants/tricyclic antidepressants* such as: amitriptyline (Elavil®), venlafaxine (Effexor®)	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*
CGRP Inhibitors		
Aimovig (erenumab)	70 mg SC once a month; may be increased to 140 mg SC once a month	140 mg/month
Ajovy (fremanezumab)	225 mg SC once a month or 675 mg SC every 3 months	225 mg/month or 675 mg/3 months
Emgality (galcanezumab)	240 mg SC as a single loading dose, followed by 120 mg SC once a month	120 mg/month
Ubrelvy (ubrogepant)	Acute migraine: 50 or 100 mg PO as needed	200 mg/day
Nurtec ODT™ (rimegepant)	75 mg PO every other day	75 mg/ every other day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): None reported
- Boxed warning(s): None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Migraine prophylaxis	10 mg, 30 mg, or 60 mg PO QD	60 mg/day

VI. Product Availability

Tablet: 10 mg, 30 mg, 60 mg

VII. References

1. Qulipta Prescribing Information. Dublin, Ireland: Allergan Pharmaceuticals International Limited, an AbbVie company; September 2021. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215206Orig1s000lbl.pdf. Accessed January 5, 2022.
2. Silberstein SD, Holland S, Freitag F, Dodick DW, Argoff C, Ashman E. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2012;78:1337-1345.
3. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache. 2019;59:1-18.
4. Pringsheim T, Davenport WJ, Becker WJ. Prophylaxis of migraine headache. *CMAJ*. 2010;182(7):E269-E276. doi:10.1503/cmaj.081657.
5. ClinicalTrials.gov. 12-Week Placebo-controlled Study of Atogepant for the Preventative Treatment of Migraine in Participants with Episodic Migraine. Available at https://www.clinicaltrials.gov/ct2/show/results/NCT03777059. Accessed January 5, 2022.
6. ClinicalTrials.gov. Efficacy, Safety, and Tolerability of Multiple Dosing Regimens of Oral Atogepant (AGN-241689) in Episodic Migraine Prevention. Available at https://clinicaltrials.gov/ct2/show/NCT02848326. Accessed January 5, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	01.05.22	02.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and

limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.