Clinical Policy: Atogepant (Qulipta)

Reference Number: CP.PHAR.566
Effective Date: 03.01.22
Last Review Date: 11.22
Line of Business: Commercial, HIM, Medicaid

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 Indication(s)

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 health plans affiliated with Centene Corporation® 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 headaches 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 2 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 at least 1 injectable CGRP therapy (e.g., Aimovig®, Ajovy®, Emgality®, Vyepti™), unless clinically significant adverse effects are experienced or all are contraindicated;
8. If currently receiving treatment with Botox® for migraine prophylaxis and request is for concurrent use of Botox and Qulipta (i.e., not switching from one agent to another), all of the following (a, b, and c):
   a. Sufficient evidence is provided from at least two high-quality*, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following (i – iv):
   **Case studies or chart reviews are not considered high-quality evidence*

i. Adequate representation of the member's clinical characteristics, age, and diagnosis;
ii. Adequate representation of the prescribed drug regimen;
iii. Clinically meaningful outcomes such as a reduction in monthly migraine or headache days;
iv. Appropriate experimental design and method to address research questions (*see Appendix D for additional information*);

b. Member has experienced and maintained positive response to Botox monotherapy as evidenced by a ≥ 30% reduction in migraine days per month from baseline following at least 2 quarterly injection (6 months) of Botox monotherapy;
c. Despite Botox monotherapy, member continues to experience ≥ 4 migraine days per month and/or severe migraine headaches that result in disability and functional impairment;

9. Qulipta is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality, Nurtec ODT, Ubrelvy, Vyepti);
10. Dose does not exceed 60 mg (1 tablet) per day.

Approval duration: 3 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member has experienced and maintained positive response to therapy as evidenced by a reduction in migraine days per months from baseline;

3. Qulipta is not prescribed concurrently with 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 (1 tablet) per day.

Approval duration: 6 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for 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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

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*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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*
Aimovig™ (erenumab-aooe)	70 mg SC once monthly Some patients may benefit from a dosage of 140 mg injected subcutaneously once monthly	140 mg/month
Ajovy® (fremanezumab-vfrm)	225 mg SC once monthly or 675 mg SC every three months	675 mg every 3 months
Emgality® (galcanezumab-gnlm)	Loading dose: 240 mg SC once Maintenance dose: 120 mg SC once monthly	120 mg/month
Vyepti™ (eptinezumab-jjmr)	The recommended dosage is 100 mg IV every 3 months. Some patients may benefit from a dosage of 300 mg IV every 3 months.	300 mg every 3 months

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

Appendix D: Appropriate Experimental Design Methods

- Randomized, prospective controlled trials are generally considered the gold standard; however:
  - In some clinical studies, it may be unnecessary or not feasible to use randomization, double-blind trials, placebos, or crossover.
  - Non-randomized prospective clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
- Case reports and chart reviews are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

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 July 27, 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 October 20, 2021.
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 October 20, 2021.
7. Ailani J, Lipton RB, Goadsby PJ, Guo H, Miceli R, Severt L, Finnegan M, Trugman JM; ADVANCE Study Group. Atogepant for the Preventive Treatment of Migraine. N Engl J Med. 2021 Aug 19;385(8):695-706.
8. Goadsby PJ, Dodick DW, Ailani J, Trugman JM, Finnegan M, Lu K, Szegedi A. Safety, tolerability, and efficacy of orally administered atogepant for the prevention of episodic migraine in adults: a double-blind, randomised phase 2b/3 trial. Lancet Neurol. 2020 Sep;19(9):727-737.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
RT4: Policy created.	11.16.21	02.22
Commercial and HIM line of business added to policy.	03.01.22	05.22
4Q 2022 annual review: Added criteria for concurrent use with Botox requiring supportive evidence from published studies or clinical practice guidelines, positive response with Botox monotherapy, and continued migraine burden; per August SDC and prior clinical guidance added redirection to injectable CGRP;	08.23.22	11.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.		

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.

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.