Clinical Policy: Atogepant (Qulipta)

Reference Number: ERX.SPA.463
Effective Date: 03.01.22
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Line of Business: 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 experiences 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. Qulipta™ is not prescribed concurrently with Botox® or other CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Nurtec®, Ubrelvy™, Vyepti™);
8. Dose does not exceed 60 mg (1 tablet) per day.

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by a reduction in migraine days per months from baseline;
3. Qulipta is not prescribed concurrently with Botox or other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality, Nurtec, 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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AAN: American Academy of Neurology
AHS: American Headaches Society
CGRP: calcitonin gene-related peptide
FDA: Food and Drug Administration
MHD: monthly headache day
MMD: monthly migraine day

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 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*

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 with or without food	60 mg/day

VI. Product Availability

Tablets: 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 October 20, 2021.
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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.16.21	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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.