

<b>Clinical Policy Title:</b>	atogepant
<b>Policy Number:</b>	RxA.713
<b>Drug(s) Applied:</b>	Qulipta™
<b>Original Policy Date:</b>	12/07/2021
<b>Last Review Date:</b>	12/07/2021
<b>Line of Business Policy Applies to:</b>	All lines of business

## Background

Atogepant (Qulipta™) is a calcitonin gene-related peptide receptor antagonist indicated for the preventive treatment of episodic migraine in adults.

## Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
atogepant (Qulipta™)	Preventive treatment of episodic migraine	10 mg, 30 mg, or 60 mg taken orally once daily with or without food. Severe Renal Impairment or End-Stage Renal Disease: 10 mg once daily.	60 mg/day orally

## Dosage Forms

- Tablets: 10 mg, 30 mg, and 60 mg

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

### I. Initial Approval Criteria

#### A. Episodic migraine in adults (must meet all):

1. Diagnosis of episodic migraine in adults;
2. Prescribed by or in consultation with a neurologist or headache specialist;
3. Age ≥ 18 years;
4. Member experiences at least 4 migraine days per month for at least 3 months;
5. Failure of at least 2 of the following oral migraine preventative therapies, each for 8 weeks and from different therapeutic classes, unless contraindicated or clinically significant adverse effects are experienced: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine);

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

6. Failure of a 3-month trial of a preferred injectable CGRP inhibitor prior to Qulipta™ (e.g. Aimovig®, Ajovy®; Emgality®);
7. Requested dose does not exceed 60 mg orally once daily.

**Approval Duration**

**Commercial:** 3 months

**Medicaid:** 3 months

**II. Continued Therapy Approval**

**A. Episodic migraine in adults** (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy and meets both of the following (a and b):
  - a. Reduction in monthly headache days by at least 2 days;
  - b. Improvement in migraine-related disability;
3. If request is for a dose increase, new dose does not exceed 60 mg orally once daily;

**Approval Duration**

**Commercial:** 6 months

**Medicaid:** 6 months

**III. Appendices**

**APPENDIX A: Abbreviation/Acronym Key**

FDA: Food and Drug Administration

CGRP: calcitonin gene-related peptide

**APPENDIX B: Therapeutic Alternatives**

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<b>Anticonvulsants</b>		
divalproex (Depakote®)	250 mg orally twice daily initially. Titrate as needed up to a maximum of 500 mg orally twice daily.	1,000 mg/day
topiramate (Topamax®)	25 mg orally every evening for 1 week, then 25 mg orally twice daily for 1 week, then 25 mg orally every morning and 50 mg orally every evening for 1 week, and then 50 mg orally twice daily	100 mg/day
<b>Beta-blockers</b>		
propranolol	Initially, 80 mg/day orally given in divided doses. May gradually increase dosage if needed to 160 to 240 mg/day. Doses of 40 to 320 mg/day orally	240 mg/day
metoprolol (Lopressor®)	Initially, 25 mg orally twice daily. Titrate to response; up to 200 mg/day orally in divided doses	400 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
timolol	Initially, 10 mg orally twice daily. May give maintenance dose of 20 mg orally once daily. Dosage range: 10 to 30 mg/day orally. Discontinue treatment after 8 weeks if maximum dosage is ineffective.	30 mg/day
<b>Antidepressants/tricyclic antidepressants*</b>		
amitriptyline	25 mg orally once daily at bedtime, initially; titrate as tolerated to efficacy. Usual effective target dose range: 75 to 100 mg orally once daily	150 mg/day orally in outpatients; 300 mg/day orally for hospitalized patients.
venlafaxine	37.5 mg orally once daily for 3 days, then 75 mg orally once daily for 3 days, followed by 150 mg orally once daily	225 mg/day orally is maximum recommended for outpatients; up to 375 mg/day orally for hospitalized inpatients.
<b>CGRP Inhibitors</b>		
Aimovig®	70 mg subcutaneously once monthly  Some patients may benefit from a dosage of 140 mg injected subcutaneously once monthly	140 mg/month
Ajovy®	225 mg subcutaneously once monthly or 675 mg subcutaneously every three months	675 mg every 3 months

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

#### APPENDIX C: Contraindications/Boxed Warnings

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

#### APPENDIX D: General Information

Due to a potential for liver injury in patients with severe hepatic impairment, avoid use of Qulipta™ in patients with severe hepatic impairment

#### References

1. Qulipta™ prescribing information. North Chicago, IL: AbbVie Inc; October 2021. Available at: [https://www.rxabbvie.com/pdf/qulipta\\_pi.pdf](https://www.rxabbvie.com/pdf/qulipta_pi.pdf). Accessed October 13, 2021.
2. Clinical Pharmacology [database online] powered by Clinical Key. Tampa, FL: Elsevier, 2020. Available at: <https://www.clinicalkey.com>. Accessed October 13, 2021.

3. IPD Analytics Rx Insights\_New Drug Approval Review\_ Qulipta \_10 2021. Accessed with subscription at: <https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Qulipta>. Accessed October 13, 2021.
4. Atogepant, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: <http://online.lexi.com>. Accessed October 13, 2021.
5. Topamax® tablets prescribing information. Titusville, NJ: Janssen Pharmaceuticals Inc; June 2021. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/020505s063,020844s054lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/020505s063,020844s054lbl.pdf). Accessed October 13, 2021.
6. Ajovy® Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; September 2021. Available at: [www.ajovy.com](http://www.ajovy.com). Accessed October 13, 2021.
7. Aimovig® Prescribing Information. Thousand Oaks, CA: Amgen Inc.; May 2021. Available at: [www.aimovig.com](http://www.aimovig.com). Accessed October 13, 2021.
8. Depakote® prescribing information. North Chicago, IL: AbbVie Inc; June 2021. Available at: <https://www.rxabbvie.com/pdf/depakote.pdf>. Accessed October 13, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	10/13/2021	12/07/2021