Qulipta (atogepant)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial request: 3 months Renewal requests: 1 year

Medications	Quantity Limit
Qulipta (atogepant)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Qulipta (atogepant) may be approved when the following criteria are met:

I. Individual has a diagnosis of episodic migraine defined as at least 4 and fewer than 15 migraine days per month and fewer than 15 headache days per month on average during the previous 3 month period; **AND**
II. Individual is using Qulipta for migraine prophylaxis;

AND
III. Documentation is provided that individual has had a trial of and inadequate response to a 2 month trial at target or usual effective dose or intolerance to two agents for migraine prophylaxis* (at least one agent in any two of the following classes) or has a contraindication to all of the following medications (AAN/AHA 2012/2015, Level A and B evidence; ICSI 2013, high quality evidence, AHS 2021). Medication samples/coupons/discount cards are excluded from consideration as a trial.:
   A. The following antidepressants: amitriptyline, venlafaxine, nortriptyline, duloxetine; **OR**
   B. One of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol; **OR**
   C. The following calcium channel blocker: verapamil; **OR**
   D. One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin;

   *Agents for migraine prophylaxis – May require Prior Authorization

AND
IV. If individual is also currently using botulinum toxin for prophylaxis and is going to be using Qulipta and botulinum toxin together (i.e., not switching from one agent to another), the following must apply:
   A. Individual has had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with botulinum toxin use; **AND**
   B. Individual continues to experience a significant number of migraine headache days or severe migraine days per month requiring additional therapy for migraine prevention.

Renewal requests for Qulipta (atogepant) may be approved when the following criteria are met:

I. Individual has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month; **AND**
II. Individual has obtained clinical benefit deemed significant by individual or prescriber including any of the following (AHS 2021):
   A. 50% reduction in frequency of days with headache or migraine; **OR**
   B. Significant decrease in attack duration; **OR**
   C. Significant decrease in attack severity; **OR**
   D. Improved response to acute treatment; **OR**
   E. Reduction in migraine-related disability and improvements in functioning in important areas of life; **OR**
   F. Improvements in health related quality of life and reduction in psychological stress due to migraine.

AND

III. If individual is using concurrently with botulinum toxin, the following must apply:
   A. Individual has had further reduction in the overall number of migraine days or reduction in number of severe migraine days per month compared to monotherapy with botulinum toxin.

Qulipta (atogepant) may **not** be approved for the following:

I. Individual is using in combination with another prophylactic CGRP agent (i.e. Aimovig, Ajovy, Emgality, Vyepti, prophylactic use of Nurtec ODT); **OR**
II. Individual has severe hepatic impairment (Child-Pugh C); **OR**
III. Individual is using requested medication for chronic migraine and has any of the following:
   A. Individual has severe renal impairment or end-stage renal disease (CrCl <30 mL/min); **OR,**
   B. Individual is currently using a strong CYP3A4 inhibitor (including but not limited to ketoconazole, itraconazole, clarithromycin); **OR,**
   C. Individual is currently using a mild, moderate, or strong CYP3A4 inducer (including but not limited to carbamazepine, phenytoin, St. John's wort, rifampin, topiramate).

Key References:

1. Beithon J, Gallenberg M, Johnson K, Kildahl P, Krenik J, Liebow M, Linbo L, Myers C, Peterson S, Schmidt J, Swanson J. Institute for Clinical Systems Improvement. Diagnosis and Treatment of Headache. Available from: icsi.org/wp-content/uploads/2019/01/Headache.pdf. Updated January 2013.
2. The International Classification of Headache Disorders 3rd Edition. Available from: https://www.ichd-3.org/. Accessed April 12, 2022.
3. Loder E, Burch R, Rizzoli P. The 2012 AHS/AAN Guidelines for Prevention of Episodic Migraine: A summary and comparison with other recent clinical practice guidelines. *Headache*. 2018; 52:930-945.
4. Rapoport AM. How to choose a preventative medication for migraine. American Headache Society. Available from: https://americanheadachesociety.org/wp-content/uploads/2018/05/Alan_Rapoport_-_Migraine_Prevention_Medications.pdf. Accessed April 12, 2022.
5. 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.

6. The American Headache Society Consensus statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021; 61:1021-1039.
7. Goadsby PJ, Dodick DW, Ailani J, et al. 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. doi: 10.1016/S1474-4422(20)30234-9. Erratum in: Lancet Neurol. 2020 Nov;19(11):e10. PMID: 32822633.
8. Ailani J, Lipton RB, Goadsby PJ, et al; ADVANCE Study Group. Atogepant for the Preventive Treatment of Migraine. N Engl J Med. 2021 Aug 19;385(8):695-706. doi: 10.1056/NEJMoa2035908. PMID: 34407343.
9. Blumenfeld AM, Frisberg BM, Schim JD, et.al. Real-world evidence for control of chronic migraine patients receiving CGRP monoclonal antibody therapy added to onabotulinumtoxinA: A retrospective chart review. Pain Ther. 21 April 2021. https://doi.org/10.1007/s40122-021-00264-x.