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 one of the following:
   A. 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; **OR**
   B. Chronic migraine defined as a headache occurring on 15 or more days per month for more than 3 months, which, on at least 8 days per month, has features of a migraine headache (ICHD-3); **AND**

II. Individual is using Qulipta for migraine prophylaxis;

AND

III. 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 the initial agent (either botulinum toxin or CGRP).

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 severe renal impairment or end-stage renal disease (CrCl <30 mL/min).

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. 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: http://bit.ly/Headache0113. Updated January 2013.
5. The International Classification of Headache Disorders 3rd Edition. Available from: https://www.ichd-3.org/. Accessed April 22, 2023.
6. 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.
7. Rapoport AM. How to choose a preventative medication for migraine. American Headache Society.
8. 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.
9. Robbins MS, Starling AJ, Pringsheim TM, Becker WJ, Schwedt TJ. Treatment of cluster headache: The American Headache Society evidence-based guidelines. *Headache*. 2016;56:1093-1106.
10. The American Headache Society Consensus statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021; 61:1021-1039.
11. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. 2024; 64: 333-341. doi:10.1111/head.14692.
12. 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. Available at: https://www.nejm.org/doi/10.1056/NEJMoa2035908?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed