Mass General Brigham
Health Plan

Calcitonin Gene-Related Peptide (CGRP) Inhibitors
Vyepti (eptinezumab-jjmr)
Effective 01/04/2027

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Vyepti (eptinezumab) is indicated for the preventive treatment of migraine in adults.

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:

1. Indication of migraine prevention
2. Member is ≥ 18 years of age
3. Appropriate dose
4. Migraine frequency ≥ 4 days per month
5. Inadequate response or adverse reaction to **TWO** or contraindication to **ALL** of the following*:
    a. beta blocker
    b. Tricyclic antidepressants (TCA)
    c. Topiramate
    d. Valproate (i.e., valproic acid, divalproex)

6. Inadequate response or adverse reaction to ONE or contraindication to ALL of the following
    a. Aimovig
    b. Ajovy
    c. Emgality

*If a prescriber specifically documents they wish to avoid a β blocker in a member due to a concurrent diagnosis of depression, this is acceptable rationale to bypass this trial. However, avoidance of a β blocker due to risk of depression in members without a documented diagnosis of depression is not adequate rationale to bypass this trial. *In addition, the following conditions can be accepted as rationale for avoidance of β blockers: asthma (bronchospastic disease), COPD, peripheral vascular disease, Raynaud's, baseline hypotension or bradycardia, and pheochromocytoma.*

Continuation of Therapy

Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

Limitations

1. Initial approvals will be granted for 3 months
2. Reauthorizations will be granted for 12 months

Appendix

Appendix A: Concomitant Therapy: Oral and Injectable

There is growing data showing efficacy and safety in using injectable CGRP inhibitors for prophylaxis therapy with oral CGRP inhibitors for acute treatment. As such, we will allow concomitant use.

- Mullin K, et al. Acute Treatment Benefit from Oral CGRP Receptor Antagonist and Monoclonal Antibody Combination: Rimegepant 75 mg for Acute Treatment of Attacks During Preventive Therapy With Erenumab. Biohaven Pharmaceuticals presentation. Diamond Headache Clinic Research & Educational Foundation Headache Update. July 25-28, 2019. Lake Buena Vista, FL.
- Mullin K, et al. 2020. Potential for Treatment Benefit of Small Molecule CGRP Receptor Antagonist Plus Monoclonal Antibody in Migraine Therapy. *Neurology.* 2020; 00: 1-5.
- NCT04179474: Safety, Tolerability & Drug Interaction Study of Ubrogepant With Erenumab or Galcanezumab in Participants With Migraine.

Appendix B: Concomitant CGRP Inhibitor and Botox Therapy

There are limited clinical trials evaluating the combination of Botox with CGRPs; however, from a clinical perspective the different mechanisms of action may provide benefit. There are several retrospective analyses available showing the benefits in headache frequency and severity. There is expert consensus that chronic migraine patients with a partial response from botulinum toxin treatment may achieve further benefits from the addition of a CGRP monoclonal antibody.

If the provider documents a partial, but incomplete, response to a CGRP inhibitor and wishes to add Botox therapy to supplement, this may be approved for 3 months. Resubmission should document response to therapy and improvement of headache days per month and can be recertified for up to 6 months.

References

1. Vyepti [prescribing information]. Bothell, WA: Lundbeck Pharmaceuticals LLC; Aug 2024
2. Tepper SJ. History and review of anti-calcitonin gene-related peptide (CGRP) therapies: from translational research to treatment. Headache. 2018;58(suppl 3):238-275. doi: 10.1111/head.13379
3. Botox (OnabotulinumtoxinA) [prescribing information]. Irvine, CA: Allergan; May 201Iclusig (ponatinib) [prescribing information]. Cambridge, MA: Ariad Pharmaceuticals Inc; October 2018
4. 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 Guideline Developer(s): 2000 Sep (revised 2012 Apr 24)
5. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia 2018; 38:1
6. Koppen H, Stolwijk J, Wilms EB, et al. Cardiac monitoring of high-dose verapamil in cluster headache: An international Delphi study. Cephalalgia 2016; 36:1385
7. Cittadini E, May A, Straube A, et al. Effectiveness of intranasal zolmitriptan in acute cluster headache: a randomized, placebo-controlled, double-blind crossover study. Arch Neurol 2006; 63:1537

8. Ekbom K, Monstad I, Prusinski A, et al. Subcutaneous sumatriptan in the acute treatment of cluster headache: a dose comparison study. The Sumatriptan Cluster Headache Study Group. Acta Neurol Scand 1993; 88:63
9. Magnoux E, Zlotnik G. Outpatient intravenous dihydroergotamine for refractory cluster headache. Headache 2004; 44:249
10. Matharu M. Cluster headache. BMJ Clin Evid 2010; 2010
11. Ekbom K, Hardebo JE. Cluster headache: aetiology, diagnosis and management. Drugs 2002; 62:61.
12. Dodick DW, Capobianco DJ. Treatment and management of cluster headache. Curr Pain Headache Rep 2001; 5:83
13. Neurol Sci. 2017 May;38(Suppl 1):45-50. doi: 10.1007/s10072-017-2924-7.
14. Cluster headache: present and future therapy: PubMed
15. Dtsch Med Wochenschr. 2017 Mar;142(6):418-426. doi: 10.1055/s-0042-121336. Epub 2017 Mar 22.[Headache Treatment].:PubMed

Review History

04/17/2019 – Reviewed
07/01/2019 – Implemented
09/18/2019 - Added cluster headaches indication to Emgality
07/22/2020 – added new formulation of Ajovy autoinjector to criteria. Effective 8/1/20.
10/06/2020 – Updated; Match Masshealth partial unified formulary requirements for implementation on 1/1/21
03/17/2021 – Reviewed and Updated; Notes were updated with acceptable diagnoses for bypassing the beta blocker for migraine prophylaxis for Ajovy, Aimovig, Emgality, and Vyepti per MH UPPL. Effective 06/01/2021.
05/18/2022 – Reviewed and Updated for May P&T; Added Appendix for Concomitant CGRP Inhibitor and Botox Therapy. Removed the following criteria from migraine prophylaxis: The member has not been treated with Botox for migraines within the past 4 months**,** member is not currently using any other CGRP or Botox for the treatment of migraines, preferred agent as Ajovy. Matched MH UPPL. Added Nurtec, Qulipta, Ubrelvy. Updated Overview section. Added migraine prophylaxis criteria for Vyepti, Nurtec, Qulipta. Added acute migraine treatment criteria for Ubrelvy and Nurtec. Removed criteria requiring specialist/neurologist consult from Emgality 100 mg/mL. Updated continuation section and duration of initial approvals/reauths based on indication. Added QLs for Nurtec (15/30), Qulipta (30/30), Ubrelvy (16/30). Matched MH UPPL. Effective 6/1/2022.
11/16/2022 – Reviewed and updated for Nov P&T; matched MH UPPL. Effective 11/1/22. Nurtec was designated as a preferred drug for migraine prevention and acute treatment of migraines. Migraine prevention criteria for Nurtec was updated to remove required steps through beta blockers and other migraine prevention therapies with mixed MOA (including topiramate, Botox, TCAs, valproic acid, and venlafaxine). Nurtec will become a required step through prior to approval of Qulipta for migraine prevention. Nurtec quantity limits changed from 15 units per month to 16 units per month.
Effective 2/1/23. Ubrelvy is designated as a preferred drug for acute treatment of migraines.
06/14/23 – Reviewed and updated for P&T. Removed preferred product criteria from Vyepti. (Not required to align MB criteria). Effective 6/30/23.
12/13/23 – Reviewed and updated for P&T. For Aimovig requests, will require a step through either Ajovy or Emgality. Effective 1/2/24
05/15/25 – Reviewed and updated for P&T. Updated formatting and references. Removed Rx drugs while medical drugs will remain on this policy as Rx drugs are available on MHDL. Effective 6/1/25
11/4/26 – Reviewed and updated for P&T. Added a step-through with Aimovig, Ajovy, and Emgality for Vyepti. Updated the duration of approval to be extended to 12 months. Updated formatting. Effective 1/4/27