# Pharmacy Medical Necessity Guidelines:
# Migraine Medications: CGRP Receptor Antagonists, and More

*Effective: January 1, 2021*

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|---|---|---|---|
| Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | SC: RX<br>IV: MED | Department to Review | RxUM/<br>RECERT |

These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink[SM] – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

**Fax Numbers:**
RXUM: 617.673.0988
PRECERT: 617.972.9409

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

## OVERVIEW

This Medical Necessity Guidelines apply to the following medications:

**Calcitonin gene-related peptide receptor (CGRP) antagonist**

- Aimovig (erenumab-aooe) injection and Ajovy (fremanezumab-vfrm) are is indicated for the preventive treatment of migraine in adults.
- Ajovy (fremanezumab-vfrm) injection is indicated for the preventive treatment of migraine in adults.
- Emgality (galcanezumab) injection is indicated in adults for preventive treatment of migraine and treatment of episodic cluster headache.
  ****Aimovig, Ajovy, and Emgality can be used for both episodic migraines and chronic migraines.*
- Nurtec (rimegepant) ODT tablet is indicated for the acute treatment of migraine with or without aura in adults.
- Ubrelvy (ubrogepant) tablet is indicated for the acute treatment of migraine with or without aura in adults.
- Vyepti (eptinezumab-jjmr) injection for intravenous use is indicated for the preventive treatment of migraine in adults.

**Serotonin $(5\text{-HT})_{1F}$ receptor agonist**

- Reyvow (lasmiditan) tablet is indicated for the acute treatment of migraine with or without aura in adults.

## COVERAGE GUIDELINES

**The plan may authorize initial coverage of Aimovig, Ajovy, or Emgality for Members, when all of the following criteria are met:**

1. The Members is 18 years of age or older

**AND**

2. The Member has a documented diagnosis of migraine headaches

**AND**

3. The Member has had an inadequate response or intolerance with an 8-week trial of two medications from any of the following classes:
   a) Beta-adrenergic blockers (e.g., metoprolol, propranolol, timolol)
   b) Antiepileptic drugs (e.g., divalproex sodium, valproic acid, topiramate)
   c) Antidepressants (e.g. amitriptyline, venlafaxine)

**AND**

4. Documentation that Member will not be using the requested agent in combination with another CGRP receptor antagonist (such as Nurtec ODT or Ubrelvy)

**AND**

5. If the request is for 140mg monthly injection of Aimovig, there is documentation that the 70mg injection was clinically insufficient

**The plan may authorize initial coverage of Emgality for treatment of episodic cluster headaches when the following criteria are met:**

1. The member has a documented diagnosis of episodic cluster headaches

**AND**

2. The member is 18 years of age or older

**The plan may authorize initial coverage of Vyepti for Members when all of the following criteria are met:**

1. The Members is 18 years of age or older

**AND**

2. The Member has a documented diagnosis of migraine headaches

**AND**

3. The Member has had an inadequate response or intolerance with an 8-week trial of two medications from any of the following classes:
    a) Beta-adrenergic blockers (e.g., metoprolol, propranolol, timolol)
    b) Antiepileptic drugs (e.g., divalproex sodium, valproic acid, topiramate)
    c) Antidepressants (e.g. amitriptyline, venlafaxine)

**AND**

4. The Member has had an inadequate response to at least a 3-month trial of one or contraindication to all of the following:
    a) Aimovig (erenumab-aooe)
    b) Emgality (galcanezumab)
    c) Ajovy (fremanezumab-vfrm)

**AND**

5. Member will not be using the requested agent in combination with another CGRP agent

**AND**

6. The requested dose is no more than 300 mg administered every 3 months

**The plan may authorize initial coverage of Nurtec ODT and Reyvow for Members, when all of the following criteria are met:**

1. The Members is 18 years of age or older

**AND**

2. Documentation that the medication will be used for **acute** treatment of migraine

**AND**

3. For members with a diagnosis of Chronic Migraine headaches (≥15 headache days per month), there is documentation that the member is using a preventive migraine medication concurrently

**AND**

4. The Member has had a contraindication, inadequate response or intolerance with at least two triptans (e.g., sumatriptan, rizatriptan)

**AND**

5. Documentation that member will not use Triptans concurrently

**AND**

6. If the request is for Nurtec ODT, there is documentation that Member will not be using the requested agent in combination with another CGRP receptor antagonist (such as Aimovig, Emgality,Ajovy, Vyepti, or Ubrelvy)

**Reauthorization criteria for all agents:**

1. Documentation is provided from the prescriber that the Member has sustained a positive response to therapy.

## LIMITATIONS

- Initial coverage for Aimovig, Emgality and Ajovy is limited to 3 months, reauthorization past 3 months may be granted for 12 months if reauthorization criteria above has been met.
- The initial coverage for Nurtec ODT, Reyvow and Vyepti is limited to 6 months, reauthorization may be granted for 12 months if reauthorization criteria above has been met.
- Members new to the plan and stable on treatment, must meet the initial criteria if on treatment for less than 3 months and must meet Reauthorization criteria if stable on treatment for more than 3 months.
- The plan does not cover concomitant therapy with Botox for migraine headaches with another long acting CGRP receptor antagonist that is indicated for prevention of chronic migraine headaches (e.g. Aimovig, Emgality, Ajovy, or Vyepti).
- Coverage of CGRPs are limited to the following quantities:

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|---|---|
| Aimovig 70 mg/mL pen | 1 pen per 30 days |
| Aimovig 140mg/mL (2 x 70 mg/mL) pen pack | 1 pack (2 pens) per 30 days |
| Ajovy 225 mg/1.5 mL prefilled syringes or auto-injector pens | 3 prefilled syringes or pens per 90 days |
| Emgality 120 mg/mL<br>(for diagnosis of migraine headaches) | • Loading dose: two consecutive subcutaneous injections of 120 mg each (total 240 mg loading dose)<br>• Maintenance: 1 auto-injector or prefilled syringe per 30 days |
| Emgality 100 mg/mL prefilled syringes<br>(for diagnosis of cluster headaches) | 3 prefilled syringes per month |
| Nurtec ODT (rimegepant) | 8 tablets per 30 days |
| Reyvow (lasmiditan) | • 50 mg tabs: 4 tablets per 30 days<br>• 100 mg tabs: 8 tablets per 30 days |

- Ubrelvy is Non-covered all Commercial and Tufts Health Direct formularies. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives and submit a formulary exception request to the plan as indicated.
- Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.

## CODES

| Code | Description |
|---|---|
| J3032 | INJECTION EPTINEZUMAB-JJMR 1 MG |

## REFERENCES


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## APPROVAL HISTORY

March 12, 2019: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- June 11, 2019: Administrative update, added limitation to clarify that samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.
- October 15, 2019: Removed Together and RITogether criteria from this Medical Necessity Guidelines. Added Emgality and Ajovy to the Medical Necessity Guidelines. Added criteria for Emgality for episodic cluster headaches. Updated the quantity limitations.
- April 14, 2020: Effective July 1, 2020, reauthorization criteria moved from limitations section up to coverage criteria. Reauthorization criteria requires documentation of a sustained positive response to therapy. Added the limitation that Members new to the plan stable on treatment, must meet Initial criteria if on treatment for less than 3 months and must meet Reauthorization criteria if stable on treatment for more than 3 months.
- June 9, 2020: Added Vyepti to the Medical Necessity Guidelines. Removed the details of number of migraine headache days from criteria: "which consists of ≥15 days per month with headache lasting 4 hours a day or longer, or 4 to 14 days per month with headache". Added Ajovy auto-injector pens to the quantity limitations section.
- July 14, 2020: Added Ubrelvy, Nurtec ODT, and Reyvow to Medical Necessity Guidelines. Renamed the title of the MNG to "Migraine Medications: CGRP Receptor Antagonists, and More". Updated the quantity limitation for Emgality 100mg to 3 pens per month and added loading dose allowance for

Emgality 120mg pens. For Aimovig, Emgality and Ajovy added criteria to clarify they can't be used in combination with another CGRP receptor antagonist (such as Ubrelvy, or Nurtec ODT)
- September 15, 2020: Effective 1/1/2021, moved Ubrelvy to Not-Covered for all Commercial and Direct. Clarified that the limitation of concurrent utilization of CGRP antagonists with Botox only applies to long acting agents that are indicated for prevention of chronic migraine headaches.

## BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.