

Pharmacy Medical Necessity Guidelines: Migraine Medications: Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists, Serotonin (5-HT) 1F Receptor Agonists, and Triptans

Effective: January 1, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	SC: RX IV: MED	Department to Review	RXUM/ PRECERT
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 			<p>Fax Numbers: RXUM: 617.673.0988 PRECERT: 617.972.9409</p>

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

OVERVIEW

Calcitonin Gene-Related Receptor (CGRP) Antagonists:

- The table below indicates Tufts Health Together’s coverage of injectable CGRP antagonists:

Medication Name	Coverage
Preferred Injectable CGRP Antagonists	
Ajovy (fremanezumab-vfrm)	PA;QL (1 injection per 30 days or 3 injections per 90 days)
Emgality (galcanezumab-gnlm) 100 mg/mL [cluster headache]	PA;QL (3 injections per 30 days)
Nonpreferred Injectable CGRP Antagonists	
Aimovig (erenumab-aooe)	PA;QL (140 mg per 30 days)
Emgality (galcanezumab-gnlm) 120 mg/mL [migraine prophylaxis]	PA;QL (2 injections for first 30 days of treatment followed by 1 injection per 30 days thereafter)
Vyepti (eptinezumab-jjmr)	Medical Benefit;PA

PA = Prior Authorization; QL = quantity limit

- Ajovy (fremanezumab-vfrm) is indicated for the preventive treatment of migraine in adults.
- Aimovig (erenumab-aooe) injection is indicated for the preventive treatment of migraine in adults. It can be used for both episodic migraines and chronic migraines.
- Emgality (galcanezumab-gnlm) 120 mg/mL injection is indicated for preventive treatment of migraine in adults. Emgality 100 mg/mL injection is indicated for treatment of episodic cluster headache.
- 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-HT) 1F Receptor Agonist

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

Triptans

- Triptan medications (serotonin 5-HT₁ receptor agonists) are indicated for the acute treatment of migraine with or without aura in adults.
- Almotriptan tablets are also indicated for the acute treatment of migraine headache pain in adolescents age 12 to 17 years of age with a history of migraine with or without aura, and who have migraine attacks usually lasting 4 hours or more.
- Rizatriptan tablets are also indicated for the acute treatment of migraine with or without aura in pediatric patients 6 to 17 years of age.
- Sumatriptan injection is also indicated for the acute treatment of cluster headache episodes in adults.
- Tufts Health Together coverage for triptan medications is as follows:

Generic Name	Brand Name	PDL Status
Covered		
Rizatriptan oral tablet	Maxalt	Covered, QL (9 tablets/30 days)
Rizatriptan orally disintegrating tablet	Maxalt ODT	Covered, QL (9 tablets/30 days)
Sumatriptan nasal solution	Imitrex nasal solution	Covered, QL (6 units/30 days)
Sumatriptan oral tablet	Imitrex tablet	Covered, QL (9 tablets/30 days)
Sumatriptan cartridge, autoinjector, syringe	Imitrex cartridge	Covered, QL (4 cartridges/autoinjectors/syringes/30 days)
Step Therapy		
Naratriptan oral tablet	Amerge oral tablet	ST, QL (9 tablets/30 days)
Zolmitriptan oral tablet	Zomig tablet	ST, QL (9 tablets/30 days)
Zolmitriptan orally disintegrating	Zomig ZMT	ST, QL (9 tablets/30 days)
Zolmitriptan nasal spray	Zomig Nasal Solution	ST, QL (6 units per 30 days)
Prior Authorization Required		
Almotriptan oral tablet	Axert tablet	PA, QL (9 tablets per 30 days)
Eletriptan oral tablet	Relpax tablet	PA, QL (9 tablets per 30 days)
Frovatriptan oral tablet	Frova tablet	PA, QL (9 tablets per 30 days)
Sumatriptan nasal spray	Tosymra	PA, QL (6 units per 30 days)

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred migraine medication when **all** of the following criteria for a particular regimen are met and limitations do not apply:

CGRP Receptor Antagonists and Serotonin (5-HT) 1F Receptor Agonists

Initial Approval Criteria

Ajovy (fremanezumab-vfrm)

1. The Member requires migraine prophylaxis
AND
2. The Member is 18 years of age or older
AND
3. Ajovy is prescribed at an appropriate dose
AND
4. The Member’s migraine frequency is at least four days per month
AND
5. The Member has had an inadequate response or adverse reaction ONE of the following or contraindication to ALL of the following (history of pharmacy claims is NOT sufficient for failed trial):
 - a. Atenolol

- b. Metoprolol
- c. Nadolol
- d. Propranolol
- e. Timolol

AND

- 6. The Member has ONE of the following:
 - a. Inadequate response or adverse reaction to ONE of the following (history of pharmacy claims is NOT sufficient for failed trial):
 - i. Tricyclic antidepressant
 - ii. Topiramate
 - iii. Valproic acid
 - iv. Venlafaxine

OR

- b. Contraindication to ALL oral less costly prophylactic alternatives (noted above)

Emgality (galcanezumab-gnlm) 100 mg/mL

- 1. The Member has a diagnosis of cluster headache

AND

- 2. The member is 18 years of age or older

AND

- 3. Emgality 100 mg/mL is prescribed at an appropriate dose

AND

- 4. The prescriber is a neurologist or a neurology consult is provided

Aimovig (erenumab-aooe), Emgality (galcanezumab-gnlm) 120 mg/mL, Vyepti (eptinezumab-jjmr)

- 1. The Member requires migraine prophylaxis

AND

- 2. The Members is 18 years of age or older

AND

- 3. The requested medication is prescribed at an appropriate dose

AND

- 4. The Member's migraine frequency is at least four days per month

AND

- 5. The prescriber is a neurologist or a neurology consult is provided

AND

- 6. The Member has had an inadequate response or adverse reaction to ONE of the following or contraindication to ALL of the following (history of pharmacy claims is NOT sufficient for failed trial):
 - a. Atenolol
 - b. Metoprolol
 - c. Nadolol
 - d. Propranolol
 - e. Timolol

AND

- 7. The Member has an inadequate response or adverse reaction to ONE of the following or contraindication to ALL of the following (history of pharmacy claims is NOT sufficient for a failed trial):
 - a. Tricyclic antidepressant
 - b. Topiramate
 - c. Valproic acid
 - d. Venlafaxine
 - e. Botox

AND

- The Member has had an inadequate response, adverse reaction or contraindication to Ajovy (history of pharmacy claims is NOT sufficient for a failed trial)

Ubrelvy (ubrogepant), Nurtec ODT (rimegepant), and Reyvow (lasmiditan)

- The Member is 18 years of age or older
AND
- Documentation that the medication will be used for **acute** treatment of migraine
AND
- 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
- The Member has had an inadequate response or intolerance with at least two triptans (e.g., sumatriptan, rizatriptan)
AND
- Documentation that member will not use triptans concurrently with the requested medication
AND
- Requests for Ubrelvy or Nurtec ODT:** Documentation that Member will not be using the requested medication in combination with another CGRP receptor antagonist

Reauthorization Criteria:

Ajovy, Aimovig, Emgality 120 mg/mL, Vyepiti, , Ubrelvy, Nurtec ODT, and Reyvow:

- Documentation from the prescriber that the Member has sustained a positive response to therapy.

Reauthorization Criteria: Emgality 100 mg/mL:

- Documentation that the member is actively having a cluster headache
AND
- The Member has been initiated on prophylactic therapy for the cluster headache (e.g., verapamil, topiramate, steroids, etc.) or the provider submits a rationale why prophylactic therapy is not appropriate.

Triptans

Naratriptan, Zolmitriptan

- The Member tried and failed therapy with both rizatriptan and sumatriptan in a similar formulation as the requested medication (if available), or the provider indicates clinical inappropriateness of treatment with both rizatriptan and sumatriptan

Almotriptan, Eletriptan, Frovatriptan

- The Member tried and failed therapy with sumatriptan and rizatriptan and at least one additional alternative generic triptan medication (e.g., naratriptan, zolmitriptan), or the provider indicates clinical inappropriateness of treatment with the preferred triptan medications

Tosymra (sumatriptan nasal spray)

- The Member tried and failed therapy with generic sumatriptan nasal spray and zolmitriptan nasal spray, or the provider indicates clinical inappropriateness of treatment with generic sumatriptan nasal spray and zolmitriptan nasal spray.

LIMITATIONS

- Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria
- Coverage is limited to the following quantities:

Medication Name	Quantity Limit
Aimovig (erenumab-aoee) 70 mg/mL pen	1 pen per 30 days
Aimovig 140 mg/mL (2 x 70 mg/mL) pen pack	1 pack (2 pens) per 30 days
Ajovy (fremanezumab-vfrm)	1 injection per 30 days or 3 injections per 90 days
Almotriptan tablet	9 tablets per 30 days
Eletriptan tablet	9 tablets per 30 days

Medication Name	Quantity Limit
Emgality 100 mg/mL [cluster headache]	3 injections per 30 days
Emgality 120 mg/mL [migraine prophylaxis]	2 injections for the 30 days per treatment followed by 1 injection per 30 days thereafter
Frovatriptan tablet	9 tablets per 30 days
Naratriptan tablet	9 tablets per 30 days
Nurtec ODT (rimegepant)	8 tablets per 30 days
Reyvow (lasmiditan)	50 mg tablets: 4 tablets per 30 days 100 mg tablets: 8 tablets per 30 days
Rizatriptan tablet, ODT	9 tablets per 30 days
Sumatriptan SC solution	4 syringes/autoinjectors/cartridges per 30 days
Sumatriptan nasal spray	6 nasal spray devices per 30 days
Sumatriptan tablet	9 tablets per 30 days
Tosymra (sumatriptan) nasal spray	6 units per 30 days
Ubrelyv (urogepant) tablets	8 tablets per 30 days
Vyepti (eptinezumab-jjmr)	3 mL per 90 days
Zolmitriptan nasal spray	6 nasal spray units per 30 days
Zolmitriptan tablet, zolmitriptan ODT	9 tablets per 30 days

- Initial coverage for Ajovy, Aimovig, Emgality 120 mg/mL, and Vyepti is limited to 3 months. Reauthorization past 3 months based on sustained clinical efficacy may be granted for 12 months.
- Initial coverage for Emgality 100 mg/mL is limited to 3 months. Reauthorization past 3 months may be granted for 3 months.
- The initial coverage for Nurtec ODT, Reyvow, and Ubrelyv is limited to 6 months. Reauthorization may be granted for 12 months if reauthorization criteria as listed above are met.
- Members new to the plan who are stable on an injectable CGRP receptor antagonist must meet initial approval criteria.
- Members new to the plan who are stable on an oral CGRP receptor antagonist or a serotonin (5HT) 1F receptor agonist must meet initial approval criteria if treatment was started less than 3 months prior to the request; members must meet reauthorization criteria if the member has been stable on treatment for 3 months or more prior to the request.
- The plan does not cover concomitant therapy with Botox for migraine headaches with another long-acting CGRP receptor antagonist indicated for the prevention of migraine headaches (e.g., Ajovy, Aimovig, Emgality 120 mg/mL, Vyepti).
- 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

None

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APPROVAL HISTORY

Triptan Medications:

June 14, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 12, 2015: Reviewed by the Pharmacy and Therapeutics Committee; approval duration modified to 2 years; renewal criteria added; criteria for naratriptan and rizatriptan modified to only require a trial w/ sumatriptan for approval; criteria for Axert, Frova and Relpax modified to require a trial w/ sumatriptan and one alternative generic triptan prior to approval; included

provider indication of clinical inappropriateness of therapy with the preferred medication(s) as criteria for approval

2. September 16, 2015: Approval duration approved for life of plan
3. January 1, 2016: Administrative change to rebranded template.
4. October 18, 2016: Reflected generic availability of Axert and Frova.
5. November 15, 2016: administrative update; removed approval duration language
6. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
7. December 12, 2017: Administrative update, reflected the generic availability of Relpax (eletriptan)
8. December 11, 2018: Administrative update, added quantity limits for all the triptan medications. Administrative changes made to template.
9. July 9, 2019: Administrative update, added the PDL status of the triptans to the background section of the MNG.
10. October 15, 2019: Added criteria for Tosymra (sumatriptan) nasal spray to the MNG.
11. April 14, 2020: Effective 4/20/20, updated the MNG to reflect that rizatriptan tablet and orally disintegrating tablet are now covered without PA. Updated criteria for naratriptan- and zolmitriptan-containing products to include rizatriptan as a trial option. Effective 7/1/2020, updated criteria for naratriptan-, zolmitriptan-, eletriptan-, frovatriptan-, and almotriptan-containing products to require trial and failure with both sumatriptan and rizatriptan.
12. July 14, 2020: Effective 7/20/20, MNG is retired. Criteria for triptan medications is being moved to MNG titled "Migraine Medications."

Migraine Medications:

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

Subsequent endorsement date(s) and changes made:

1. 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.
2. October 15, 2019: Criteria for Together was separated from the Commercial Medical Necessity Guidelines. Clarified that Ajoyv and Emgality are not covered.
3. June 9, 2020: Added criteria for Vyepti.
4. July 14, 2020: Added criteria for Reyview, Ubrelvy, and Nurtec ODT. Combined MNGs for CGRP receptor antagonists, serotonin (5HT) 1F receptor agonists, and triptans. Updated Aimovig criteria to clarify that member will not be approved if the agent will be used in combination with another CGRP receptor antagonist. Clarified which criteria to apply (i.e., initial vs reauthorization) for CGRP receptor antagonists and serotonin (5HT) 1F receptor agonists when member is new to the Plan and already on the requested medication. Added quantity limit information for Vyepti. Renamed MNG to "Migraine Medications."
5. November 24, 2020: Effective January 1, 2021, updated Aimovig and Vyepti approval criteria. Added Ajoyv and Emgality to the MNG. Updated reauthorization criteria for CGRP receptor antagonists. Updated initial and reauthorization approval duration for Vyepti. Updated limitations section of MNG to specify that members new to the plan stable on an injectable CGRP receptor antagonist must meet initial approval criteria.

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.

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