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

Effective: July 20, 2020

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

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℠ – 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

Calcitonin Gene-Related Receptor (CGRP) Antagonists:

- 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.
- 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-HT_1 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 RITogether 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 (ODT)	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 tablet (ODT)	Zomig ZMT	ST, QL (9 tablets/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 nasal spray	PA, QL (6 units per 30 days)
Zolmitriptan nasal spray	Zomig Nasal Solution	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:

Aimovig (erenumab-aooe)

1. The Members is 18 years of age or older

AND

2. The Member has a documented diagnosis of migraine headaches, 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

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:
    - Beta-adrenergic blockers (e.g., metoprolol, propranolol, timolol)
    - Antiepileptic drugs (e.g., divalproex sodium, valproic acid, topiramate)
    - Antidepressants (e.g. amitriptyline, venlafaxine)

AND

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

AND

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

Vyepti (eptinezumab-jjmr)

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 to at least a 3-month trial of or contraindication to Aimovig

AND

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

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

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

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 an inadequate response or intolerance with at least generic two triptans (e.g., sumatriptan, rizatriptan)

AND

5. Documentation that member will not use triptans concurrently with the requested medication

AND

6. **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 (CGRP Receptor Antagonists and Serotonin (5-HT) 1F Receptor Agonists):

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

Triptans

Naratriptan, zolmitriptan tablets

1. 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 generic sumatriptan and rizatriptan.

Almotriptan-, eletriptan-, frovatriptan-containing product or zolmitriptan nasal spray

1. 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)

1. The Member tried and failed therapy with generic sumatriptan nasal spray as well as zolmitriptan nasal spray and one additional generic triptan, or the provider indicates clinical inappropriateness of treatment with generic sumatriptan nasal spray, zolmitriptan nasal spray, and an additional generic triptan.

LIMITATIONS

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

Medication Name	Quantity Limit
Aimovig 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
Almotriptan tablet	9 tablets per 30 days
Eletriptan tablet	9 tablets per 30 days
Frovatriptan tablet	9 tablets per 30 days
Naratriptan tablet	9 tablets per 30 days
Nurtect 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
Ubrelvy (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

3. Initial coverage for Aimovig is limited to 3 months. Requests for continuation of therapy will be approved for 12 months if reauthorization criteria are met.
4. The initial coverage for Ubrelvy, Nurtec ODT, Reyvow, and Vyepti is limited to 6 months. Requests for continuation of therapy will be approved for 12 months if reauthorization criteria are met.
5. Members new to the plan who are stable on a CGRP receptor antagonist or 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.
6. 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., Aimovig, Vyepti).
7. Ajovy and Emgality are not covered.
8. 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

REFERENCES

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APPROVAL HISTORY

Triptans 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. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.

7. December 12, 2017: Administrative update, reflected 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: Updated criteria for zolmitriptan nasal spray. Updated criteria for generic naratriptan, rizatriptan and zolmitriptan to specify member must try and fail generic sumatriptan. Added PDL status of medications to background section of 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-, almotriptan-containing products and zolmitriptan nasal spray to require trial and failure with both sumatriptan and rizatriptan.
12. July 14, 2020: Effective 7/20/20, retiring "Triptans" MNG. Criteria for triptan medications 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 RI-Together was separated from the Commercial Medical Necessity Guidelines. Clarified that Ajovy and Emgality are not covered.
3. June 9, 2020: Added criteria for Vyepti.
4. July 14, 2020: Added criteria for Reyvew, Ubrelvy, and Nurtec ODT. Combined MNGs for CGRP receptor antagonists, serotonin (5-HT) 1F receptor agonists, and triptans. Updated Aimovig criteria to clarify that the member will not be approved if the agent will be used in combination with another CGRP receptor antagonist. Updated length of approval for Vyepti. 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."

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.