

Pharmacy Medical Necessity Guidelines: Triptan Medications

Effective: July 14, 2020

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

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Adults

Amerge (naratriptan) tablets, Axert (almotriptan) tablets, Frova (frovatriptan) tablets, Imitrex (sumatriptan) tablets, Imitrex (sumatriptan) nasal spray, Maxalt (rizatriptan) tablets, Maxalt-MLT (rizatriptan orally disintegrating tablets), Onzetra Xsail (sumatriptan), Relpax (eletriptan) tablets, Treximet (sumatriptan and naproxen sodium) tablets, Zomig (zolmitriptan) tablets, Zomig-ZMT (zolmitriptan orally disintegrating tablets), and Zomig (zolmitriptan) nasal spray are indicated for the acute treatment of migraine attacks with or without aura in adults. These drugs are not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of 5HT-1 agonist tablets have not been established for cluster headache, which is present in an older, predominantly male population.

Imitrex (sumatriptan) injection is indicated for the acute treatment of migraine attacks with or without aura and the acute treatment of cluster headache episodes. Imitrex (sumatriptan) injection is not intended for the prophylactic therapy of migraine or cluster headache attacks (Imitrex [sumatriptan] injection). Imitrex (sumatriptan) injection is not for use in the management of hemiplegic or basilar migraine.

Pediatrics and Adolescents

Axert (almotriptan) tablets are indicated for the acute treatment of migraine headache pain in adolescents age 12 to 17 years with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated). The efficacy of Axert (almotriptan) tablets on migraine associated symptoms (nausea, photophobia and phonophobia) was not established.

Maxalt (rizatriptan) tablets and Maxalt-MLT (rizatriptan orally disintegrating tablets) are indicated for the acute treatment of migraine with or without aura in pediatric patients 6 to 17 years of age.

Treximet (sumatriptan and naproxen sodium) tablets and Zomig (zolmitriptan) nasal spray are indicated for the acute treatment of migraine with or without aura in pediatric patients 12 years and older.

COVERAGE GUIDELINES

Note: Prescriptions that meet the initial step therapy requirements, will adjudicate **automatically** at the point of service. If the Member does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan using the Universal Pharmacy Medical Review Request Form for Members who do not meet the step therapy criteria at the point of service.

Please refer to the table below for formularies and medications subject to this policy:

DRUG	Tufts Health Plan Large Group Plans	Tufts Health Plan Small Group and Individual Plans
Step-1		
frovatriptan	Covered	Covered
sumatriptan		
almotriptan		
naratriptan		
rizatriptan		
rizatriptan soluble tablet		
zolmitriptan		
zolmitriptan soluble tablet		
eletriptan		
Step-2		
Onzetra Xsail	Requires prior use of a drug on Step-1 or Step-2	Requires prior use of a drug on Step-1 or Step-2
Zomig nasal spray		

Automated Step Therapy Coverage Criteria

The following stepped approach applies to coverage of the Step-2 medications by the plan:

Step 1: Medications on Step-1 are covered without prior authorization

Step 2: The plan may cover Step-2 medications if the following criteria are met:

- The Member has had a trial of a Step-1 or Step-2 medication within the previous 180 days as evidenced by a paid claim under the prescription benefit administered by the plan

Note: The plan may cover medications on Step-2 if a Member has received one of the **non-covered** brand name medications, listed below under the limitations section, within the previous 180 days.

Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

Step 2: The plan may cover medications on Step-2 if the following criteria are met:

- The Member has had a trial of a Step-1 or Step-2 medication as evidenced by physician documented use, excluding the use of samples

Note: The plan may cover medications on Step-2 if a Member has received one of the **non-covered** brand name medications, listed below under the limitations section, within the previous 180 days.

Generic Treximet (sumatriptan and naproxen sodium) tablets

Generic Treximet (sumatriptan and naproxen sodium) tablets may be covered if **ALL** of the following criteria are met:

- Member is 12 years of age or older
- AND**
- Documented diagnosis of acute migraine with or without aura
- AND**
- Member has tried and failed the individual ingredients (sumatriptan and naproxen sodium) used together

LIMITATIONS

- The plan does not authorize coverage of non-covered medications through this step therapy program. 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.
- The plan does not cover the following for all Commercial formularies: Amerge, Axert, Frova, Imitrex, Maxalt, Maxalt MLT, Relpax, Treximet, Zembrance Symtouch, Zomig tablets, and Zomig ZMT. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives.
- Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.
- The following quantity limitations apply for any strength and combination of the following Migraine Therapy. Please refer to the Pharmacy Medical Necessity Guidelines for Drugs with Dispensing Limitations and submit a formulary exception request with clinical justification for those Members requiring higher quantities.

Amerge tablets	9 tablets per 30 days
Axert (almotriptan) tablets	6 tablets per 30 days
eletriptan tablets	6 tablets per 30 days
Frova tablets	9 tablets per 30 days
Imitrex injection	4 injections (2 kits)/30 days or 4 injections (4 vials) per 30 days
Imitrex nasal spray	5 mg: 2 boxes (12 spray unit devices) per 30 days 20 mg: 1 box (6 spray unit devices) per 30 days
Imitrex tablets	9 tablets per 30 days
Maxalt/Maxalt-MLT	9 tablets per 30 days
naratriptan	9 tablets per 30 days
Onzetra Xsail nasal powder	8 pouches per 30 days
Relpax	6 tablets per 30 days
rizatriptan/rizatriptan soluble tablet	9 tablets per 30 days
sumatriptan injection	4 injections (2 kits) per 30 days or 4 injections (4 vials) per 30 days
sumatriptan nasal spray	5 mg: 2 boxes (12 spray unit devices) per 30 days 20 mg: 1 box (6 spray unit devices) per 30 days
sumatriptan tablets	9 tablets per 30 days
sumatriptan and naproxen sodium tablets	9 tablets per 30 days
Treximet tablets	9 tablets per 30 days
zolmitriptan/zolmitriptan soluble tablets	2.5 mg: 6 tablets per 30 days 5 mg: 3 tablets per 30 days
Zomig spray	1 box (6 spray units)/30 days
Zomig tablets	2.5 mg: 6 tablets per 30 days 5 mg: 3 tablets per 30 days
Zomig-ZMT	2.5 mg: 6 tablets per 30 days 5 mg: 3 tablets per 30 days

CODES

None

REFERENCES

1. Amerge (naratriptan) [package insert]. Research Triangle Park, NC: GlaxoSmithKline; Dec 2016.
2. Axert (almotriptan) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; May 2017.
3. Derry CJ, Derry S, Moore RA. Sumatriptan (intranasal route of administration) for acute migraine attacks in adults. *Cochrane Database Syst Rev*. 2012 Feb 15; 2:CD009663.
4. Derry CJ, Derry S, Moore RA. Sumatriptan (oral route of administration) for acute migraine attacks in adults. *Cochrane Database Syst Rev*. 2012 Feb 15; 2:CD008615.
5. Derry CJ, Derry S, Moore RA. Sumatriptan (subcutaneous route of administration) for acute migraine attacks in adults. *Cochrane Database Syst Rev*. 2012 Feb 15; 2:CD009665.
6. Frova (frovatriptan) [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; Oct 2013.
7. Imitrex (sumatriptan) injection [package insert]. Research Triangle Park, NC: GlaxoSmithKline; Nov 2015.
8. Imitrex (sumatriptan) tablets [package insert]. Research Triangle Park, NC: GlaxoSmithKline; Nov 2013.
9. Law S, Derry S, Moore RA. Triptans for acute cluster headache. *Cochrane Database Syst Rev*. 2010 Apr 14; (4):CD008042.
10. Lewis D, Ashwal S, Hershey A, et al. Practice parameter: pharmacological treatment of migraine headache in children and adolescents: report of the American Academy of Neurology Quality Standards Subcommittee and the Practice Committee of the Child Neurology Society. *Neurology*. 2004 Dec 28; 63(12):2215-24.
11. Maxalt / Maxalt-MLT (rizatriptan) [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; Oct 2019.
12. Onzetra Xsail (sumatriptan) [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc.; Oct 2016.

13. Relpax (eletriptan) [package insert]. New York, NY: Pfizer Inc.; Nov 2013.
14. Silver S, Gano D, Gerretsen P. Acute treatment of pediatric migraine: a meta-analysis of efficacy. *J Paediatr Child Health*. 2008 Jan; 44(1-2):3-9.
15. Treximet (sumatriptan and naproxen) [package insert]. Morristown, NJ: Pernix Ireland Limited; July 2019.
16. Winner P, Landy S, Richardson M, et al. Early intervention in migraine with sumatriptan tablets 50 mg versus 100 mg: a pooled analysis of data from six clinical trials. *Clin Ther*. 2005 Nov; 27(11):1785-94.
17. Zomig (zolmitriptan nasal spray) [package insert]. Bridgewater, NJ: Amneal Specialty Pharma; May 2019.
18. Zomig/Zomig-ZMT (zolmitriptan) [package insert]. Bridgewater, NJ: Amneal Specialty Pharma; May 2019.

APPROVAL HISTORY

July 13, 2010: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 14, 2010: Added naratriptan to Step-1 of the Migraine Medications Step Therapy program.
2. January 11, 2011: Adjusted the coverage of the brand name drugs for the GFF; Amerge, Axert, Imitrex, Relpax, and Sumavel Dosepro are not covered. Added Alsuma to Step-2 of the Migraine Medications Medical Necessity Guidelines. Added limitation: Tufts Health Plan does not authorize coverage of non-covered medications through this step therapy program. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives and submit a formulary exception request to Tufts Health Plan as indicated.
3. January 10, 2012: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
4. June 12, 2012: Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs. Clarified step criteria to reflect that Step-2 drugs are prerequisites for drugs on Step-2.
5. August 14, 2012: Added limitation that the brand name products Alsuma, Amerge, Axert, Imitrex, Relpax, Sumavel Dosepro are not covered on the Tufts Health Plan Generic Focused Formulary (GFF). Added limitation that Treximet is not covered. Treximet may qualify as prerequisite for Step-2 drugs. Added use of samples or vouchers/coupons for brand name medications limitation.
6. February 12, 2013: Added rizatriptan and rizatriptan soluble tablet to Step-1 and moved Maxalt/Maxalt MLT to not covered for the Generic Focused Formulary.
7. June 11, 2013: Added zolmitriptan and zolmitriptan soluble tablet to Step-1 and moved Zomig/Zomig ZMT to not covered for the Generic Focused Formulary.
8. October 8, 2013: Administrative update: Removed requirement of 30-day trial and replaced with just a previous trial of the medication.
9. April 1, 2014: Administrative Update: Removed language pertaining to the Generic Focused Formulary and added EHB MA/RI Formulary.
10. June 10, 2014: No changes.
11. March 10, 2015: For effective date April 1, 2015: Moved Amerge, Imitrex, Maxalt, and Maxalt MLT to not covered for the MA/RI EHB formularies.
12. October 6, 2015: Effective January 1, 2016: Zomig tablets, Zomig ZMT, and Axert will be non-covered for the Exchange formularies.
13. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
14. April 12, 2016: Added generic frovatriptan to Step-1. Moved Frova® to not covered for the MA/RI EHB formularies.
15. July 12, 2016: Added Onzetra Xsail to Step-2 for all Commercial Formularies.
16. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
17. July 11, 2017: No changes.
18. September 12, 2017: Removed Alsuma from criteria due to discontinuation by manufacturer. Added generic eletriptan to Step-1. Moved Relpax to not covered for the MA/RI EHB formularies.
19. March 13, 2018: Added criteria for generic Treximet tablets. Moved brand Axert, Amerge, Frova, Imitrex, Maxalt, Maxalt-MLT, Relpax, Zomig tablets and Zomig-ZMT tablets to not covered for Tufts Health Plan Commercial Large Groups. Updated the limitation section to reflect brand Treximet is not covered across all Commercial formularies and both brand and generic Treximet have a quantity limitation of 9 tablets per 30 days.
20. October 16, 2018: Administrative updates- Removed the Non-Covered drugs from the Step-Therapy table. Administrative update to template.

21. November 12, 2019: Removed Sumavel DosePro from the MNG, as the product was discontinued. Added Zembrance Symtouch to the list of non-covered medications. No changes to criteria.
22. July 14, 2020: Changed the title of the MNG from "Migraine Medications" to "Triptan Medications" to clarify this MNG does not apply to other classes of migraine management drugs such as CGRP receptor antagonists, etc.

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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