

Clinical Policy: Triptans

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Line of Business: Medicaid – Medi-Cal

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The following are triptans requiring prior authorization: Amerge[®], Axert[®], Frova[®], Imitrex[®], Maxalt[®]/Maxalt MLT[®], Relpax[®], Treximet[®] and Zomig[®].

FDA approved indication

Amerge, Frova, Imitrex, Relpax, Zomig/Zomig-ZMT tablet is indicated:

- For the acute treatment of migraine attacks with or without aura in adults.

Axert is indicated:

- For the acute treatment of migraine attacks in adults with a history of migraine with or without aura.
- For the acute treatment of migraine headache pain in adolescents age 12 to 17 years with a history of migraine with or without aura, and who have migraine attacks usually lasting 4 hours or more.

Maxalt, Maxalt MLT

- Acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years of age.

Treximet and Zomig nasal spray is indicated:

- For the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation[®] that Amerge, Axert, Frova, Imitrex, Maxalt/Maxalt MLT, Relpax, Treximet and Zomig are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Migraines (must meet all):

1. Diagnosis of migraine headaches;
2. For non-preferred triptans (including Frova, Relpax, Zomig, Treximet, Maxalt/Maxalt MLT):

- a. Failure of two formulary 5HT₁-agonist migraine medications (e.g., naratriptan (Amerge), almotriptan (Axert) or oral sumatriptan (Imitrex)) at maximum tolerable doses, unless contraindicated or clinically significant adverse effects are experienced;
 - b. For members age 6 to 11 years, Maxalt/Maxalt MLT may be approved;
 - c. For members age 12 to 17 years, Treximet and Maxalt/Maxalt MLT may be approved after a trial of Axert;
3. Requests for monthly quantities greater than the health plan limit, one of the following (a or b):
 - a. Failure of two prophylactic migraine medications unless contraindicated or clinically significant adverse effects are experienced;
 - b. Patient is being treated by a neurologist or a headache specialist;
4. For all Treximet requests: Medical justification must be provided why individual generic components of sumatriptan and naproxen cannot be used.

Approval duration: Length of Benefit (quantity limits apply)

B. Cluster Headaches (Imitrex Nasal Spray only) (must meet all):

1. Diagnosis of cluster headache attacks confirmed by a neurologist or headache specialist;
2. Request is for Imitrex nasal spray;

Approval duration: Length of Benefit (quantity limits apply)

C. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Member is responding positively to therapy.

Approval duration: Length of Benefit (quantity limits apply)

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Centene Corporation and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.PMN.53 or evidence of coverage documents;
- B.** Management of hemiplegic or basilar migraines;

- C. Concurrent administration with MAO inhibitors or use within 2 weeks of discontinuation of MAO inhibitor therapy (Imitrex and Zomig only).

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AAN: American Academy of Neurology

CABG: coronary artery bypass graft

Appendix B: General Information

- Black Box Warning for Treximet stating NSAIDs may cause an increased risk of serious cardiovascular events and increased of gastrointestinal events. Treximet is also contraindicated in the setting of coronary artery bypass graft (CABG) surgery.
- All Triptans are contraindicated in patients with history of coronary artery disease or coronary vasospasm; symptomatic Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders; history of stroke, transient ischemic attack, or hemiplegic or basilar migraine, or peripheral vascular disease; ischemic bowel disease; or uncontrolled hypertension. Also with recent (within 24 hours) used of another 5-HT₁ agonist (e.g., another triptan), or an ergotamine-containing medication.
- Relpax (ONLY) is contraindicated within at least 72 hours of treatment with the following potent CYP3A4 inhibitors: ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir or nelfinavir.
- The triptans should not be used for hemiplegic or basilar migraines
- Imitrex and Zomig are metabolized by monoamine oxidase A (MAO-A), and inhibitors of this enzyme may increase serum concentrations of these triptans. Use of Imitrex or Zomig concurrently or within 2 weeks of discontinuation of an MAO-A inhibitor or non-selective MAO inhibitor is contraindicated.
- AAN guidelines for cluster headaches support the use of Imitrex Nasal Spray for acute treatment (Level B). Intranasal sumatriptan at a dose of 20 mg has been shown to be effective in the acute treatment of cluster headache.
- According to AAN guidelines, verapamil, lithium and melatonin may be considered for the prevention of cluster headaches.
- The American Academy of Neurology recommends that prophylactic migraine medications should be considered if the patient experiences 2 or more attacks per month that produce aggregate disability of 3 or more days/month.

Preventive Therapies for Migraine (Adopted by the American Academy of Neurology)		
Medication	Dose	Level of Evidence**
<i>Anticonvulsants</i>		
divalproex sodium (Depakote®)	500-1000 mg/day PO	FDA Approved
divalproex sodium ER (Depakote® ER)	500-1000 mg/day PO	FDA Approved
gabapentin (Neurontin®)	900-2400 mg/day PO	Group II
topiramate (Topamax®)	100 mg/day PO	FDA Approved
<i>Beta-Blockers</i>		

Preventive Therapies for Migraine (Adopted by the American Academy of Neurology)		
Medication	Dose	Level of Evidence**
atenolol (Tenormin®)	100 mg/day PO	Group II
metoprolol (Lopressor®)	200 mg/day PO	Group II
nadolol (Corgard®)	80-240 mg/day PO	Group II
propranolol (Inderal®)	80-240 mg/day PO	Group I
timolol (Blocadren®)	20-30 mg/day PO	Group I
Calcium Channel Blockers		
verapamil (Calan®)	240 mg/day PO	Group II
SSRIs		
fluoxetine (Prozac®)	20 mg QOD - 40 mg/day PO	Group II
Tricyclic Antidepressants		
amitriptyline (Elavil®)	30-150 mg/day PO	Group I
imipramine (Tofranil®)	Not Established	Group III
nortriptyline (Pamelor®)	Not Established	Group III

**Group I = Medium to high efficacy, good strength of evidence, and mild to moderate side effects; Group II = Lower efficacy than Group I, or limited strength of evidence, and mild to moderate side effects; Group III = Clinically efficacious

Appendix C: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
butalbital/APAP/caffeine (Fioricet)	1 - 2 tablets PO Q 4hr	6 tablets/day
butalbital/ASA/caffeine (Fiorinal)	1 - 2 tablets PO Q 4hr	6 tablets/day
ergotamine/caffeine (Cafergot)	1 - 2 tablets PO Q 30 min PRN	6 mg/day (ergotamine) 10 mg/week (ergotamine)
isometheptene/dichloralphenazone/APAP (Midrin)	2 capsules PO at onset then 1 capsule Q 1 hour PRN	5 capsules/12 hours
naratriptan (Amerge)	1 or 2.5 mg PO QD May repeat dose in 4 hours	5 mg/24 hours
sumatriptan (Imitrex) tablet	25 to 100 mg PO QD May repeat dose in 2 hours	200 mg/24 hours
sumatriptan nasal spray (Imitrex)	One spray (5-20 mg) intranasally at onset into one nostril; can repeat in 2 hours.	40 mg/24 hours

*Requires Prior Authorization

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
naratriptan (Amerge)	1 or 2.5 mg PO QD May repeat dose in 4 hours	5 mg/24 hours
rizatriptan (Maxalt/ Maxalt MLT)	5 or 10 mg PO QD May repeat dose in 2 hours Pediatrics: <40 kg: 5 mg PO QD (MAX: 1 dose/24 hr) ≥40 kg: 10 mg PO QD (MAX: 1 dose/24 hr)	30 mg/24 hours
sumatriptan (Imitrex) tablet	25 to 100 mg PO QD May repeat dose in 2 hours	200 mg/24 hours
almotriptan (Axert)	6.25 to 12.5 mg PO QD May repeat dose in 2 hours	25 mg/24 hours
Frovatriptan (Frova)	2.5 mg PO QD May repeat dose in 2 hours	7.5 mg/24 hours
sumatriptan nasal spray (Imitrex)	One spray (5-20 mg) intranasally at onset into one nostril May repeat dose in 2 hours	40 mg/24 hours
eletriptan (Relpax)	20 or 40 mg PO QD May repeat dose in 2 hours	Single dose: 40 mg Daily dose: 80 mg
zolmitriptan (Zomig and Zomig ZMT)	1.25 or 2.5 mg PO QD May repeat dose in 2 hours	Single dose: 5 mg Daily dose: 10 mg
zomig nasal (zolmitriptan)	2.5 mg intranasally into one nostril May repeat dose in 2 hours	Single dose: 5 mg Daily dose: 10 mg

<i>sumatriptan /naproxen (Treximet)</i>	85 mg sumatriptan/500 mg naproxen PO QD May repeat dose in 2 hours <u>Pediatrics: 12 to 17 years of age</u> 10 mg sumatriptan/60 mg naproxen PO QD	<u>Adults:</u> 170 mg sumatriptan/ 1000 mg naproxen /24 hours (* safety of treating an average of more than 5 headaches/30 days is not established) <u>Pediatrics: 12 to 17 years of age</u> 85 mg sumatriptan/500 mg naproxen /24 hours (*safety of treating an average of more than 2 headaches/30 days is not established)
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VI. Product Availability

Drug	Availability
naratriptan (Amerge)	Tablet: 1 mg, 2.5 mg (package size 9)
almotriptan (Axert)	Tablet: 6.25 mg (package size 6), 12.5mg (package size 12)
frovatriptan (Frova)	Tablet: 2.5 mg (package size 9)
Rizatriptan (Maxalt)	Tablet: 5 mg, 10 mg (package size 6, 9, 12, 18)
Rizatriptan (Maxalt MLT)	Tablet: 5 mg, 10 mg (package size 3, 6)
sumatriptan (Imitrex)	Tablet: 25 mg, 50 mg, 100 mg (package size 9)
sumatriptan nasal spray (Imitrex Nasal)	Nasal spray: 5 mg, 20 mg (package size 6)
eletriptan (Relpax)	Tablet: 20 mg (package size 6), 40 mg (package size 6, 12)
zolmitriptan (Zomig)	Tablet: 2.5 mg (package size 6), 5 mg (package size 3)
zolmitriptan nasal spray (Zomig Nasal Spray)	Nasal spray: 2.5 mg, 5 mg (package size 6)
zolmitriptan orally disintegrating (Zomig ZMT)	Tablet: 2.5 mg (package size 6), 5 mg (package size 3)
sumatriptan-naproxen (Treximet)	Tablet: 85 mg sumatriptan and 500 mg naproxen sodium (package size 9, 12), 10 mg sumatriptan and 60 mg naproxen sodium (package size 9)

VII. References

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2. Axert [Prescribing Information] Raritan, NJ: Ortho-Mc-Neil-Janssen; May 2017.

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7. Frova [Prescribing Information] Chadds Ford, PA: Endo; October 2013.
8. Relpax [Prescribing Information] New York, NY: Pfizer; September 2013.
9. Treximet [Prescribing Information] Morristown, NJ: Pernix Therapeutics; May 2016.
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14. Francis GJ, Becker WJ, Pringsheim TM. Acute and preventive pharmacologic treatment of cluster headache. *Neurology* 2010;75:463-73.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; minor changes to verbiage and grammar. References updated.	06.15.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the

administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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