

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS 5-HT₁ AGONISTS, COMBINATIONS (ALL DOSAGE FORMS)

BRAND NAME
(generic)

(almotriptan)

AMERGE
(naratriptan)

FROVA
(frovatriptan)

IMITREX
(sumatriptan)

MAXALT/MAXALT-MLT
(rizatriptan)

ONZETRA XSAIL
(sumatriptan)

RELPAK
(eletriptan)

TOSYMRA
(sumatriptan)

TREXIMET
(sumatriptan/naproxen)

ZEMBRACE SYMTOUCH
(sumatriptan)

ZOMIG / ZOMIG-ZMT
(zolmitriptan)

Status: CVS Caremark Criteria

Type: Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Almotriptan

Adults: Almotriptan tablets are indicated for the acute treatment of migraine attacks in patients with a history of migraine with or without aura.

Adolescents Age 12 to 17 Years: Almotriptan tablets are indicated for the acute treatment of migraine headache pain in patients with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated).

Limitations of Use:

Almotriptan tablets should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with almotriptan tablets, the diagnosis of migraine should be reconsidered before almotriptan tablets are administered to treat any subsequent attacks. In adolescents age 12 to 17 years, efficacy of almotriptan tablets on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Almotriptan tablets are not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of almotriptan tablets have not been established for cluster headache which is present in an older, predominantly male population.

Amerge

Amerge is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use:

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Amerge, reconsider the diagnosis of migraine before Amerge is administered to treat any subsequent attacks. Amerge is not indicated for the prevention of migraine attacks. Safety and effectiveness of Amerge have not been established for cluster headache.

Frova

Frova tablets are indicated for the acute treatment of migraine attacks with or without aura in adults.

Limitations of Use:

Use only if a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Frova, reconsider the diagnosis of migraine before Frova is administered to treat any subsequent attacks. Frova is not indicated for the prevention of migraine attacks. Safety and effectiveness of Frova have not been established for cluster headache.

Imitrex Injection

Imitrex Injection is indicated in adults for (1) the acute treatment of migraine, with or without aura, and (2) the acute treatment of cluster headache.

Limitations of Use:

Use only if a clear diagnosis of migraine or cluster headache has been established. If a patient has no response to the first migraine or cluster headache attack treated with Imitrex Injection, reconsider the diagnosis before Imitrex Injection is administered to treat any subsequent attacks. Imitrex is not indicated for the prevention of migraine or cluster headache attacks.

Imitrex Nasal Spray and Imitrex Tablets

Imitrex Nasal Spray and Imitrex Tablets are indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use:

Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Imitrex, reconsider the diagnosis of migraine before Imitrex is administered to treat any subsequent attacks. Imitrex is not indicated for the prevention of migraine attacks. Safety and effectiveness of Imitrex nasal spray and Imitrex tablets have not been established for cluster headache.

Maxalt-MLT and Maxalt

Maxalt-MLT and Maxalt are indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years old.

Limitations of Use:

Maxalt should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Maxalt, the diagnosis of migraine should be reconsidered before Maxalt is administered to treat any subsequent attacks. Maxalt is not indicated for use in the management of hemiplegic or basilar migraine. Maxalt is not indicated for the prevention of migraine attacks. Safety and effectiveness of Maxalt have not been established for cluster headache.

Onzetra Xsail

Onzetra Xsail is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use:

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Onzetra Xsail, reconsider the diagnosis of migraine before treatment of subsequent attacks with Onzetra Xsail. Onzetra Xsail is not indicated for the prevention of migraine attacks. Safety and effectiveness of Onzetra Xsail have not been established for the treatment of cluster headache.

Relpax

Relpax tablets are indicated for the acute treatment of migraine attacks with or without aura in adults.

Limitations of Use:

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Relpax, reconsider the diagnosis of migraine before treatment of subsequent attacks with Relpax. Relpax is not indicated for the prevention of migraine attacks. Safety and effectiveness of Relpax have not been established for the treatment of cluster headache.

Tosymra

Tosymra is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use:

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Tosymra, reconsider the diagnosis before Tosymra is administered to treat any subsequent attacks. Tosymra is not indicated for the preventive treatment of migraine. Tosymra is not indicated for the treatment of cluster headache.

Treximet

Treximet is indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.

Limitations of Use:

Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Treximet, reconsider the diagnosis of migraine before Treximet is administered to treat any subsequent attacks. Treximet is not indicated for the prevention of migraine attacks. Safety and effectiveness of Treximet have not been established for cluster headache.

Zembrace SymTouch

Zembrace SymTouch is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use:

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Zembrace SymTouch, reconsider the diagnosis before Zembrace SymTouch is administered to treat any subsequent attacks. Zembrace SymTouch injection is not indicated for the prevention of migraine attacks.

Zomig Nasal Spray

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.

Limitations of Use:

Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache. Not recommended in patients with moderate or severe hepatic impairment.

Zomig Tablets and Zomig-ZMT

Zomig is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use:

Zomig should only be used if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache.

Compendial Uses¹⁶

Imitrex Nasal Spray

Acute treatment of cluster headache

Onzetra Xsail

Acute treatment of cluster headache

Tosymra

Acute treatment of cluster headache

Zomig Nasal Spray

Acute treatment of cluster headache

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient does not have confirmed or suspected cardiovascular or cerebrovascular disease, or uncontrolled hypertension

AND

- The patient has a diagnosis of migraine headache

AND

- The patient is currently using migraine prophylactic therapy

[Note: examples of prophylactic therapy are divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, venlafaxine.]

OR

- The patient is unable to take migraine prophylactic therapies due to inadequate treatment response, intolerance or contraindication

[Note: examples of prophylactic therapy are divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, venlafaxine.]

AND

- Medication overuse headache has been considered and ruled out

OR

- The request is for sumatriptan injection, sumatriptan nasal spray, or zolmitriptan nasal spray (e.g., Imitrex Injection, Imitrex Nasal Spray, Onzetra Xsail, Tosymra, Zomig NS) for the treatment of cluster headache

AND

- The requested drug is not being used concurrently with another triptan 5-HT₁ agonist

OR

- The requested drug is being used concurrently with another triptan 5-HT₁ agonist AND the patient requires more than one triptan 5-HT₁ agonist due to clinical need for differing routes of administration

Current plan approved criteria cover an amount for treating eight headaches per month at a maximum daily dose up to:

18 tablets/month of almotriptan tablets

18 tablets/month of Amerge Tablets (naratriptan)

27 tablets/month of Frova Tablets (frovatriptan)

18 vials/month of Imitrex single-dose vial (sumatriptan) 6mg/0.5mL

18 syringe cartridges/month of Imitrex prefilled syringe (sumatriptan) 6mg/0.5mL

27 syringe cartridges/month of Imitrex prefilled syringe (sumatriptan) 4mg/0.5mL

18 nasal units/month of Imitrex Nasal Spray (sumatriptan) 20mg

36 nasal units /month of Imitrex Nasal Spray (sumatriptan) 5mg

18 tablets/month of Imitrex Tablets (sumatriptan)

27 tablets/month of Maxalt/Maxalt-MLT Tablets (rizatriptan)

32 nosepieces (2 kits or 16 pouches)/month of Onzetra Xsail Nosepiece (sumatriptan)

18 tablets/month of Relpax Tablets (eletriptan)

24 nasal units/month of Tosymra nasal spray (sumatriptan) 10mg

18 tablets/month of Treximet Tablets (sumatriptan)

36 auto-injectors/month of Zembrace SymTouch (sumatriptan)

18 tablets/month of Zomig/Zomig-ZMT Tablets (zolmitriptan)

18 nasal units/month of Zomig Nasal Spray (zolmitriptan)

REFERENCES

1. Almotriptan malate [package insert]. Bridgewater, NJ: Ajanta Pharma USA Inc. April 2020.
2. Amerge [package insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2020.

3. Frova [package insert]. Chadds Ford, PA: Endo Pharmaceuticals Inc.; August 2018.
4. Imitrex Injection [package insert]. Research Triangle Park, NC: GlaxoSmithKline; September 2020.
5. Imitrex Nasal Spray [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
6. Imitrex Tablets [package insert]. Research Triangle Park, NC: GlaxoSmithKline; September 2020.
7. Maxalt and Maxalt-MLT [package insert]. Whitehouse Station, NJ: Merck & Co., Inc; September 2020.
8. Onzetra Xsail [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc.; December 2019.
9. Relpax [package insert]. New York, NY: Pfizer, Inc.; March 2020.
10. Tosymra [package insert]. Princeton, NJ: Promius Pharma, LLC; January 2019.
11. Treximet [package insert]. Morristown, NJ: Pernix Therapeutics, LLC; April 2021.
12. Zembrace SymTouch [package insert]. Princeton, NJ: Promius Pharma LLC; June 2019.
13. Zomig Nasal Spray [package insert]. Hayward, CA: Impax Pharmaceuticals Inc.; May 2019.
14. Zomig Tablets and Zomig-ZMT [package insert]. Hayward, CA: Impax Pharmaceuticals Inc.; May 2019.
15. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: UpToDate, Inc.; 2021: Accessed June 2021.
16. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed June 2021.
17. Silberstein S, Holland S, Freitag F, et al. Evidence-Based Guideline Update: Pharmacologic Treatment for Episodic Migraine Prevention in Adults: Report of the Quality and the American Headache Society Standards Subcommittee of the American Academy of Neurology. *Neurology* 2012;78;1337-1346.
18. Oskoui M, Pringsheim T, Billingshurst L et al. Practice guideline update summary: Pharmacologic treatment for pediatric migraine prevention: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology* 2019;93:500-509.
19. Law S, Derry S, and Moore RA. Triptans for acute cluster headache (Review). The Cochrane Collaboration; *Cochrane Database of Systematic Reviews* 2013; Issue 7.
20. Robbins MS, Starling AJ, Pringsheim TM et al. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. *Neurology* 2016;56:1093-1106.
21. Van Vliet J, Bahra A, Martin V, et al. Intranasal Sumatriptan in Cluster Headache, Randomized Placebo-Controlled Double-Blind Study. *Neurology* 2003;60:630-633.
22. Rapoport A, Mathew N, Silberstein S. et al. Zolmitriptan Nasal Spray in the Acute Treatment of Cluster Headache, A double-blind study. *Neurology* 2007;69:821-826.
23. Cittadini E, May A, Straube A, Effectiveness of Intranasal Zolmitriptan in Acute Cluster Headache, A Randomized, Placebo-Controlled, Double-blind Crossover Study. *ArchNeurol.* 2006;63. <http://www.archneurol.com/>. Accessed June 2020.
24. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. *Headache* 2019;59:1-18.
25. Oskoui M, Pringsheim T, Holler-Managan Y, et al. Practice guidelines update summary: Acute treatment of migraine headache in children and adolescents: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology* 2019;93;487-499.