

PRIOR AUTHORIZATION CRITERIA

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

BRAND NAME

(generic)

(almotriptan)

AMERGE

(naratriptan)

FROVA

(froatriptan)

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 is 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 and Maxalt-ML

Maxalt and Maxalt-MLT 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 is 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 Relpax is administered to treat any subsequent attacks. 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:

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.

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 Nasal Spray) 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

Quantity Limits apply.

POST LIMIT QUANTITY

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

Medication	Strength	Maximum dose per 24 hours	1 Month Limit *	3 Months Limit *
almotriptan	6.25 mg	2 tablets**	18 tablets / 25 days	54 tablets / 75 days
	12.5 mg	2 tablets 25 mg		
Amerge (naratriptan)	1 mg	2 tablets**	18 tablets / 25 days	54 tablets / 75 days
	2.5 mg	2 tablets 5 mg		
Frova (frovatriptan)	2.5 mg	3 tablets 7.5 mg	27 tablets / 25 days	81 tablets / 75 days
Imitrex Injection (sumatriptan) single dose vials	6 mg	2 injections 12 mg	18 vials (9mL) / 25 days	55 vials (27.5mL) / 75 days
Imitrex Injection (sumatriptan) syringes STATdose / Refill	4 mg	3 injections 12 mg	27 syringes (13.5mL) / 25 days	81 syringes (40.5mL) / 75 days
	6 mg	2 injections	18 syringes (9mL) / 25 days	54 syringes (27mL) / 75 days

		12 mg		
Imitrex Nasal Spray (sumatriptan)	5 mg	4 sprays**	36 units / 25 days	108 units / 75 days
	20 mg	2 sprays 40 mg	18 units / 25 days	54 units / 75 days
Imitrex Tablets (sumatriptan)	25mg, 50mg	2 tablets**	18 tablets / 25 days	54 tablets / 75 days
	100 mg	2 tablets 200 mg		
Maxalt Maxalt-MLT (rizatriptan)	5 mg	3 tablets**	27 tablets / 25 days	81 tablets / 75 days
	10 mg	3 tablets 30 mg		
Onzetra Xsail (sumatriptan)	11mg	4 nosepieces 44mg	32 nosepieces / 25 days (2 kits, 16 pouches)	96 nosepieces / 75 days (6 kits, 48 pouches)
Relpax (eletriptan)	20 mg	2 tablets**	18 tablets / 25 days	54 tablets / 75 days
	40 mg	2 tablets 80 mg		
Tosymra (sumatriptan)	10 mg	3 sprays 30 mg	24 units / 25 days	72 units / 75 days
Treximet (sumatriptan/naproxen)	85mg/500mg	1-2 tablets 170mg/1000mg	18 tablets / 25 days	54 tablets / 75 days
Zembrace SymTouch (sumatriptan)	3 mg	4 injections 12mg	36 autoinjectors (18mL) / 25 days	108 autoinjectors (54mL) / 75 days
Zomig Nasal Spray (zolmitriptan)	2.5 mg	2 sprays**	18 units / 25 days	54 units / 75 days
	5 mg	2 sprays 10 mg		
Zomig Tablets Zomig-ZMT (zolmitriptan)	2.5 mg	2 tablets**	18 tablets / 25 days	54 tablets / 75 days
	5 mg	2 tablets 10 mg		
* The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.				
**Utilize higher strength available.				

REFERENCES

1. Almotriptan [package insert]. Bridgewater, NJ: Ajanta Pharma USA Inc. November 2021.
2. Amerge [package insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2020.
3. Frova [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; August 2018.
4. Imitrex Injection [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2021.
5. Imitrex Nasal Spray [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
6. Imitrex Tablets [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2020.
7. Maxalt and Maxalt-MLT [package insert]. Jersey City, NJ: Organon LLC; June 2021.
8. Onzetra Xsail [package insert]. Morristown, NJ: Currax Pharmaceuticals LLC; December 2019.
9. Relpax [package insert]. New York, NY: Pfizer, Inc.; March 2020.
10. Tosymra [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; February 2021.
11. Treximet [package insert]. Morristown, NJ: Currax Therapeutics, LLC; April 2021.
12. Zembrace SymTouch [package insert]. Maple Grove, MN: Upsher-Smith Laboratories LLC; February 2021.
13. Zomig Nasal Spray [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2019.
14. Zomig and Zomig-ZMT [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2019.
15. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, Ohio: UpToDate, Inc.; 2022: Accessed June 1, 2021.
16. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed June 1, 2022.
17. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology* 2012;78;1337-1346.
18. American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache* 2021;61:1021-1039.
19. 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.

20. Oskoui M, Pringsheim T, Holler-Managan Y, et al. Practice guideline 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.
21. Law S, Derry S, Moore RA. Triptans for acute cluster headache (Review). The Cochrane Collaboration; *Cochrane Database Syst Rev* 2013;7.
22. Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. *Headache* 2016;56:1093-1106.
23. Francis GJ, Becker WJ, Pringsheim TM. Acute and preventative pharmacologic treatment of cluster headache. *Neurology* 2010;75:463-473.
24. Van Vliet JA, Bahra A, Martin V, et al. Intranasal sumatriptan in cluster headache, Randomized placebo-controlled double-blind study. *Neurology* 2003;60:630-633.
25. Cittadini E, May A, Straube A, et al. Effectiveness of Intranasal Zolmitriptan in Acute Cluster Headache, A Randomized, Placebo-Controlled, Double-blind Crossover Study. *Arch Neurol* 2006;63:E1-E6.
26. Rapoport AM, Mathew NT, Silberstein SD, et al. Zolmitriptan nasal spray in the acute treatment of cluster headache, A double-blind study. *Neurology* 2007;69:821-826.