

QUANTITY LIMIT CRITERIA

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

BRAND NAME*
(generic)

AMERGE
(naratriptan)

AXERT
(almotriptan)

FROVA
(frovatriptan)

IMITREX
(sumatriptan)

MAXALT/MAXALT-MLT
(rizatriptan)

ONZETRA XSAIL
(sumatriptan)

RELPAX
(eletriptan)

SUMAVEL DosePro
(sumatriptan)

TOSYMRA
(sumatriptan)

TREXIMET
(sumatriptan/naproxen)

ZEMBRACE SYMTOUCH
(sumatriptan)

ZOMIG / ZOMIG-ZMT
(zolmitriptan)

Status: CVS Caremark Criteria
Type: Quantity Limit

Ref # 2-H

**Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Amerge

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

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.

Axert

Adults: Axert (almotriptan malate) is 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: Axert is 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).

Axert 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 Axert, the diagnosis of migraine should be reconsidered before Axert is administered to treat any subsequent attacks. In adolescents age 12 to 17 years, efficacy of Axert on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Axert is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of Axert have not been established for cluster headache which is present in an older, predominantly male population.

Frova

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

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.

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.

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 pediatric patients 6 to 17 years old.

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.

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.

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.

Sumavel DosePro

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

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

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.

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.

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.

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.

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.

RATIONALE

According to the American Headache Society, all patients should be offered acute migraine treatment. Some patients may require additional preventive treatment based on attack frequency or degree of disability. Patients with migraine should be considered for preventive treatment in any of the following situations: attacks significantly interfere with patients' daily routines despite acute treatment; frequent attacks (≥ 4 migraine headache days); a contraindication to, failure, or overuse of acute treatments; adverse events with acute treatments; or patient preference.¹⁸ Based on these recommendations, patients requiring treatment for more than 4 migraine headache days per month should be evaluated further for preventive treatment. The limits are set at a quantity sufficient to treat at least 4 headaches per month and up to 6 headaches per month at maximum recommended daily dosing, based on manufacturer package sizes. 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 in the Limit Criteria chart.

Because their vasospastic effects may be additive, coadministration of another 5-HT₁ agonists (e.g., triptans) within 24 hours of each other is contraindicated.

If the patient is requesting more than the initial quantity limit the system will reject with a message indicating that a prior authorization is needed.

Amerge

The recommended dose of Amerge is 1mg or 2.5mg. The dose may be repeated once after 4 hours, for a maximum dose of 5 mg in a 24-hour period.

Axert

The recommended dose of Axert in adults and adolescents age 12 to 17 years is 6.25mg to 12.5mg. The dose may be repeated after 2 hours. The maximum daily dose should not exceed 25mg.

Frova

The recommended dose is a single tablet of Frova 2.5mg. A second tablet may be taken providing there is an interval of at least two hours between doses. The total daily dose of Frova should not exceed three tablets (7.5mg).

Imitrex

Injection

The maximum single recommended adult dose of Imitrex Injection for the acute treatment of migraine or cluster headache is 6mg injected subcutaneously. For the treatment of migraine, if side effects are dose limiting, lower doses (1 mg to 5 mg) may be used. For the treatment of cluster headache, the efficacy of lower doses has not been established. The maximum cumulative dose that may be given in 24 hours is 12mg, two 6-mg injections separated by at least 1 hour.

Nasal Spray

Single doses of 5mg, 10mg or 20mg of Imitrex Nasal Spray administered into one nostril are effective for the acute treatment of migraine in adults. A 10mg dose may be achieved by the administration of a single 5mg dose in each nostril. The dose may be repeated once after 2 hours, not to exceed a total daily dose of 40mg.

Tablets

Single doses of 25mg, 50mg or 100mg of Imitrex tablets are effective for the acute treatment of migraine in adults. The dose may be repeated after 2 hours, not to exceed a total daily dose of 200mg.

Maxalt and Maxalt-MLT

The recommended starting dose of Maxalt is either 5mg or 10mg for the acute treatment of migraines in adults. A second dose may be administered 2 hours after the first dose. The maximum daily dose should not exceed 30mg in any 24-hour period. Dosing in pediatric patients is based on the patient's body weight. The recommended dose of Maxalt is 5mg in patients weighing less than 40kg, and 10mg in patients weighing 40kg or more.

Onzetra Xsail

The recommended dosage of Onzetra Xsail is 22mg of sumatriptan nasal powder (2 nosepieces). A second dose of 22mg may be administered at least 2 hours after the first dose. The maximum recommended dose that may be given in 24 hours is two doses of Onzetra Xsail (44mg/4 nosepieces).

Onzetra Xsail is supplied as a nosepiece containing a capsule with 11mg sumatriptan base. Onzetra Xsail is available in kits containing 8 doses. 1 kit contains 8 pouches of 2 nosepieces (22mg sumatriptan) per pouch and 2 delivery system bodies.

Relpax

Single doses of 20mg and 40mg are effective for the acute treatment of migraine in adults. If a second dose is required, it should be taken at least two hours after the initial dose. The maximum daily dose should not exceed 80mg.

Sumavel DosePro

The maximum single recommended dose of Sumavel DosePro for the acute treatment of migraine or cluster headache is 6mg given subcutaneously. For the treatment of migraine, if side effects are dose limiting, a lower dose (4mg) may be used. For the treatment of cluster headache, the efficacy of a lower dose has not been established. The maximum cumulative injected dose that may be given in 24 hours is 12mg, with doses of Sumavel DosePro separated by at least 1 hour.

Tosymra

The recommended dosage for adults is 10mg given as a single spray in one nostril. The maximum cumulative dose that may be given in a 24-hour period is 30 mg, with doses of TOSYMRA separated by at least 1 hour. TOSYMRA may also be given at least 1 hour following a dose of another sumatriptan product.

Treximet

The recommended dosage for adults is one 85/500mg tablet. The maximum recommended dosage of Treximet 85/500mg in a 24-hour period is two tablets, taken at least 2 hours apart.

The recommended dosage for pediatric patients 12 to 17 years of age is 1 tablet of Treximet 10/60mg. The maximum recommended dosage in a 24-hour period is 1 tablet of Treximet 85/500mg.

Treximet is available in bottles of 9 tablets. Do not repackage; dispense and store in original container with desiccant.

Zembrace SymTouch

The recommended dose of Zembrace SymTouch is 3mg injected subcutaneously.

The maximum cumulative dose that may be given in 24 hours is 12mg, with doses separated by at least 1 hour.

Zomig and Zomig-ZMT

Nasal Spray

The recommended starting dose for Zomig Nasal Spray in adult and pediatric patients 12 years of age and older is 2.5mg. The maximum recommended single dose of Zomig is 5mg. If the migraine has not resolved by 2 hours or returns after a transient improvement, another dose may be administered at least 2 hours after the previous dose. The maximum daily dose should not exceed 10mg in any 24-hour period.

Tablets

Single doses of 1.25mg, 2.5mg and 5mg of Zomig tablets and 2.5mg and 5mg of Zomig-ZMT are effective for the acute treatment of migraines in adults. The dose may be repeated after two hours, not to exceed 10mg within a 24 hour period.

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 Date Written: 03/1998
 Revised: 07/1998; (LS) 10/2000, 12/2000, 03/2001, 05/2001, 10/2001, 4/2002;(JG) 01/2003 (Relpax added), 10/2003 (Zomig NS added); (RP) 01/2004; (JG) 07/2004, 07/2005; (AK) 02/2006; (CT) 06/2006; (AM) 07/2007; (CT) 04/2008(2) (Treximet added); (AM) 07/2008, 07/2009; (KD) 07/2010; (CY) 05/2011; (RDP/TM) 04/2013, (TM) 12/2013 (add Zomig NS 2.5mg), (RP/TM) 05/2014, 10/2014 (add Sumavel 4mg), (TM) 05/2015, 09/2015 (remove Zecuity-Specialty), (TM) 02/2016 (add Onzetra Xsail and Zembrace SymTouch), (TM) 05/2016 (no clinical changes), 05/2017 (add mL to limits) 06/2017 (remove Alsuma, adjust Onzetra, Treximet QL); (KC) 06/2018 (no clinical changes), 02/2019 (added Tosymra), 06/2019 (no clinical changes)
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LIMIT CRITERIA

The intent is for the patient to receive only one drug from this drug class at a time.

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	Dose per headache	Maximum dose per 24 hours	Package Size	1 Month Limit * 3 Months Limit *
Amerge (naratriptan)	1 mg	1-2 tablets	2 tablets**	9 tablets	12 tablets / 25 days 36 tablets / 75 days
	2.5 mg	1-2 tablets	2 tablets 5 mg		
Axert (almotriptan)	6.25 mg	1-2 tablets	2 tablets**	6 tablets	12 tablets / 25 days 36 tablets / 75 days
	12.5 mg	1-2 tablets	2 tablets 25 mg	12 tablets	
Frova (frovatriptan)	2.5 mg	1-2 tablets	3 tablets 7.5 mg	9 tablets	18 tablets / 25 days 54 tablets / 75 days
Imitrex Injection (sumatriptan) vials	6 mg	1-2 injections	2 injections 12 mg	5 single dose vials 0.5mL each	12 vials (6mL) / 25 days 40 vials (20mL) / 75 days
Imitrex Injection (sumatriptan) syringes STATdose / Refill	4 mg	1-2 injections	3 injections 12 mg	2 prefilled syringes 0.5mL each	18 syringes (9mL) / 25 days 54 syringes (27mL) / 75 days
	6 mg	1-2 injections	2 injections 12 mg		
Imitrex Nasal Spray (sumatriptan)	5 mg	1-4 sprays	4 sprays**	6 nasal spray units	24 units / 25 days 72 units / 75 days
	20 mg	1-2 sprays	2 sprays 40 mg		
Imitrex Tablets (sumatriptan)	25mg, 50mg	1-2 tablets	2 tablets**	9 tablets	12 tablets / 25 days 36 tablets / 75 days
	100 mg	1-2 tablets	2 tablets 200 mg		
Maxalt Maxalt-MLT (rizatriptan)	5 mg	1-2 tablets	3 tablets**	18 tablets 3 orally disintegrating tablets	18 tablets / 25 days 54 tablets / 75 days
	10 mg	1-2 tablets	3 tablets 30 mg	18 tablets 3 orally disintegrating tablets	

Onzetra Xsail (sumatriptan)	11 mg	2 nosepieces	4 nosepieces 44mg	16 nosepieces – 2 nosepieces per pouch 8 pouches per kit	16 nosepieces / 25 days (1 kit, 8 pouches) 64 nosepieces / 75 days (4 kits, 32 pouches)
Relpax (eletriptan)	20 mg	1-2 tablets	2 tablets**	6 tablets	12 tablets / 25 days 36 tablets / 75 days
	40 mg	1-2 tablets	2 tablets 80 mg	6 tablets 12 tablets	
Sumavel DosePro (sumatriptan)	4 mg	1-2 injections	3 injections 12 mg	6 injections 0.5mL each	18 injections (9mL) / 25 days 54 injections (27mL) / 75 days
	6 mg	1-2 injections	2 injections 12 mg		12 injections (6mL) / 25 days 36 injections (18mL) / 75 days
Tosymra (sumatriptan nasal)	10 mg	1-3 sprays	3 sprays 30 mg	6 nasal spray units	18 units / 25 days 54 units / 75 days
Treximet (sumatriptan/naproxen)	10mg/60mg	1 tablet	1 tablet** 10mg/60mg	9 tablets dispense in original container	9 tablets / 25 days 18 tablets / 75 days
	85mg/500mg	1-2 tablets	1-2 tablets 170mg/1000mg		9 tablets / 25 days 36 tablets / 75 days
Zembrace SymTouch (sumatriptan)	3 mg	1-4 injections	4 injections 12mg	4 autoinjectors 0.5mL each	24 injectors (12mL) / 25 days 72 injectors (36mL) / 75 days
Zomig Nasal Spray (zolmitriptan)	2.5 mg	1-2 sprays	2 sprays**	6 nasal spray units	12 units / 25 days 36 units / 75 days
	5 mg	1-2 sprays	2 sprays 10 mg		
Zomig Tablets Zomig-ZMT (zolmitriptan)	2.5 mg	1/2-2 tablets	2 tablets**	6 tablets	12 tablets / 25 days 36 tablets / 75 days
	5 mg	1-2 tablets	2 tablets 10 mg	3 tablets	

* 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, unless otherwise stated.

*The limit criteria apply to both brand and generic, if available.

**Utilize higher strength available.