

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	5-HT₁ AGONISTS, COMBINATIONS (ALL DOSAGE FORMS)		
BRAND NAME (generic)	ALSUMA (sumatriptan)	AMERGE (naratriptan)	AXERT (almotriptan)
MLT	FROVA (frovatriptan)	IMITREX (sumatriptan)	MAXALT/ MAXALT- (rizatriptan)
	ONZETRA XSAIL (sumatriptan)	RELPAK (eletriptan)	SUMAVEL DosePro (sumatriptan)
	TREXIMET (sumatriptan/naproxen)	ZEMBRACE SYMTOUCH (sumatriptan)	ZOMIG / ZOMIG-ZMT (zolmitriptan)
Status: CVS Caremark Criteria			
Type: Post Limit Prior Authorization			

Zecuity is not included and clients should implement the Specialty UM if they so desire.

POLICY

FDA-APPROVED INDICATIONS

Alsuma

Alsuma (sumatriptan injection) is indicated in adults for the acute treatment of migraine, with or without aura, and 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 Alsuma, reconsider the diagnosis of migraine before Alsuma is administered to treat any subsequent attacks.

Alsuma is not indicated for the prevention of migraine attacks.

Amerge

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

Amerge tablets are not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar. Safety and effectiveness of Amerge tablets have not been established for cluster headache, which is present in an older, predominantly male population.

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.

Frova is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. The safety and effectiveness of Frova have not been established for cluster headache, which is present in an older, predominately male, population.

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Imitrex Injection

Imitrex Injection is indicated for the acute treatment of migraine attacks, with or without aura, and the acute treatment of cluster headache episodes.

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 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.

Imitrex Nasal Spray and Imitrex Tablets

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

Imitrex Nasal Spray and 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 Imitrex Nasal Spray and Tablets have not been established for cluster headache, which is present in an older, predominantly male population.

Maxalt-MLT and Maxalt Tablets

Maxalt-MLT and Maxalt Tablets are indicated for the acute treatment of migraine attacks with or without aura in adults. 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.

Relpax is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of Relpax Tablets have not been established for cluster headache, which is present in an older, predominantly male population.

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.

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, 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. Zomig nasal spray is not recommended in patients with moderate or severe hepatic impairment.

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COMPENDIAL USE

Imitrex Nasal Spray

Acute treatment of cluster headache

Zomig Nasal Spray

Acute treatment of cluster headache

COVERAGE CRITERIA

5-HT1 Agonists 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.
- The patient is not treating more than eight headaches per month with a 5-HT1 agonist.

AND

- The patient has a diagnosis of migraine headache.
 - The patient is currently using migraine prophylactic therapy or unable to take migraine prophylactic therapies due to inadequate response, intolerance or contraindication.
[Note: examples of prophylactic therapy are divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, venlafaxine.]
 - Medication overuse headache has been considered and ruled out.

OR

- The patient has a diagnosis of cluster headache.
 - The request is for Alsuma, Imitrex (sumatriptan) Injection, Imitrex (sumatriptan) Nasal Spray, Sumavel DosePro, or Zomig Nasal Spray.

POST LIMIT QUANTITY FOR APPROVAL

The post limit quantity chart below should be used to determine the quantity for approval for each prescribed medication.

***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. **Zecuity is not included and clients should implement the Specialty UM if they so desire.**

Medication	Strength	1 Month Limit*	3 Month Limit*
Alsuma Injection (sumatriptan)	6mg / 0.5mL	18 auto-injectors	54 auto-injectors
Amerge Tablets (naratriptan)	1mg, 2.5mg	18 tablets	54 tablets
Axert Tablets (almotriptan)	6.25mg, 12.5mg	18 tablets	54 tablets
Frova Tablets (frovatriptan)	2.5mg	27 tablets	81 tablets
Imitrex single-dose vial (sumatriptan)	6mg/0.5mL	18 vials	55 vials
Imitrex prefilled syringe (sumatriptan)	4mg/0.5mL	27 syringe cartridges	81 syringe cartridges
Imitrex prefilled syringe (sumatriptan)	6mg/0.5mL	18 syringe cartridges	54 syringe cartridges
Imitrex Nasal Spray (sumatriptan)	5mg	36 nasal units	108 nasal units
Imitrex Nasal Spray (sumatriptan)	20mg	18 nasal units	54 nasal units
Imitrex Tablets (sumatriptan)	25mg, 50mg, 100mg	18 tablets	54 tablets
Maxalt/Maxalt-MLT Tablets (rizatriptan)	5mg, 10 mg	27 tablets	81 tablets
Onzetra Xsail Nosepiece (sumatriptan)	11mg	2 kits (16 pouches, 32 nosepieces)	6 kits (48 pouches, 96 nosepieces)
Relpax Tablets (eletriptan)	20mg, 40mg	18 tablets	54 tablets
Sumavel DosePro (sumatriptan)	4mg / 0.5mL	27 syringes	81 syringes
Sumavel DosePro (sumatriptan)	6mg / 0.5mL	18 syringes	54 syringes
Treximet Tablets (sumatriptan)	10mg / 60mg	18 tablets	27 tablets
Treximet Tablets (sumatriptan)	85mg / 500mg	18 tablets	54 tablets
Zembrace SymTouch (sumatriptan)	3mg / 0.5mL	36 auto-injectors	108 auto-injectors
Zomig/Zomig-ZMT Tablets (zolmitriptan)	2.5mg, 5mg	18 tablets	54 tablets
Zomig Nasal Spray (zolmitriptan)	2.5mg,5mg	18 nasal units	54 nasal units

* 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.

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