# **QUANTITY LIMIT 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)					
	RELPAX (eletriptan)					
	TOSYMRA (sumatriptan)					
	TREXIMET (sumatriptan/naproxen)					
	ZEMBRACE SYMTOUCH (sumatriptan)					
	ZOMIG / ZOMIG-ZMT (zolmitriptan)					

Type: Quantity Limit

## 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.

5-HT1 Agonist Limit Policy 2-H 07-2021.docx

©2021 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

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). 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:

5-HT1 Agonist Limit Policy 2-H 07-2021.docx

©2021 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

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. <u>Limitations of Use</u>:

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.

#### **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; June 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. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache 2019;59:1-18.

## 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 *
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	6 tablets 12 tablets	
Amerge (naratriptan)	1 mg	1-2 tablets	2 tablets**		12 tablets / 25 days 36 tablets / 75 days
	2.5 mg	1-2 tablets	2 tablets 5 mg	9 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		12 syringes (6mL) / 25 days 36 syringes (18mL) / 75 days
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		12 units / 25 days 36 units / 75 days
Imitrex Tablets (sumatriptan)	25mg, 50mg	1-2 tablets	2 tablets**	9 tablets (brand and generic) 27, 36, 90, 100 tablets (generic)	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**	12, 18 tablets (generic), 3, 9, 12, 18 orally disintegrating tablets (generic)	18 tablets / 25 days 54 tablets / 75 days
	10 mg	1-2 tablets	3 tablets 30 mg	18 tablets (brand and generic) 12 tablets (generic), 3 orally disintegrating tablets (brand and generic), 9, 12, 18 orally disintegrating tablets (generic)	

5-HT1 Agonist Limit Policy 2-H 07-2021.docx

©2021 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

Onzetra Xsail (sumatriptan)	11mg	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	
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)	85mg/500mg	1-2 tablets	1-2 tablets 170mg/1000mg	9 tablets dispense in original container	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 da 36 units / 75 da	12 upite / 25 days
	5 mg	1-2 sprays	2 sprays 10 mg		36 units / 75 days
Zomig Tablets Zomig-ZMT (zolmitriptan)	2.5 mg	1/2-2 tablets	2 tablets**	6 tablets	<ul> <li>12 tablets / 25 days</li> <li>36 tablets / 75 days</li> </ul>
	5 mg	1-2 tablets	2 tablets 10 mg	3 tablets	
* The duration of 25 days **Utilize higher strength a		day fill period and	d 75 days is used fo	or a 90-day fill period to allow t	ime for refill processing.