

Initial Step Therapy; Post Step Therapy Prior Authorization Symbravo, Treximet

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Symbravo	meloxicam/rizatriptan
Treximet	sumatriptan/naproxen

Indications

FDA-approved Indications

Symbravo

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

Limitations of Use

Symbravo should only be used where a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Symbravo, the diagnosis of migraine should be reconsidered before Symbravo is administered to treat any subsequent attacks. Symbravo is not indicated for the preventive treatment of migraine attacks. Symbravo 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.

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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.

Initial Step Therapy

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 30-day supply of generic sumatriptan AND generic naproxen OR generic meloxicam AND generic rizatriptan within the past 120 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Coverage Criteria

Authorization may be granted when the requested drug is being prescribed for the diagnosis of migraine headache when ALL of the following criteria are met:

- The patient has tried and experienced an inadequate treatment response or intolerance to THREE triptan 5-HT1 agonists
- The patient has tried the two individual components of the requested drug taken together [i.e., (meloxicam plus rizatriptan) or (naproxen plus sumatriptan)]

Duration of Approval (DOA)

• 3020-D: DOA: 12 months

References

- 1. Symbravo [package insert]. New York, NY: Axsome Therapeutics, Inc.; January 2025.
- 2. Treximet [package insert]. Brentwood, TN: Currax Pharmaceuticals LLC; February 2024.
- 3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed April 1, 2024.

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- 4. Micromedex[®] (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 04/01/2024).
- 5. American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache 2021;61:1021-1093.
- 6. Oskoui M, Pringsheim T, Holler-Managen Y, et al. Practice guideline update: Acute treatment of migraine 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

Document History

Written by:UM Development (KC)

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CRITERIA FOR APPROVAL					
1	Does the patient have a diagnosis of migraine headache? [If Yes, then go to 2. If No, then no further questions.]	Yes	No		
2	Has the patient tried and experienced an inadequate treatment response or intolerance to THREE triptan 5-HT1 agonists? [If Yes, then go to 3. If No, then no further questions.]	Yes	No		
3	Has the patient tried the two individual components of the requested drug taken together [i.e., (meloxicam plus rizatriptan) or (naproxen plus sumatriptan)]? [No further questions]	Yes	No		

Mapping Instructions			
	Yes	No	DENIAL REASONS

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1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for migraine headache. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Deny	Your plan only covers this drug if you have tried other drugs and they did not work well for you. We have denied your request because: A) You have not tried three triptan 5-HT1 agonists, and B) You do not have a medical reason not to take them. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy - three triptans]
3.	Approve, 12 Months	Deny	Your plan only covers this drug if you have tried the individual drugs (meloxicam plus rizatriptan) or (naproxen plus sumatriptan) together and it did not work well for you. We have denied your request because you have not tried it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy - individual components]

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