

5.70.03

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Analgesics and Anesthetics	Original Policy Date:	March 5, 2005
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Last Review Date: March 12, 2021

Amerge

Description

Amerge (naratriptan)

Background

The selective serotonin receptor agonists, or "triptans", are a class of medications that have the ability to stop a migraine. Triptans work by binding to serotonin receptors in the brain. Specifically, per Drug Facts and Comparisons pharmacology of the Serotonin 5-HT₁ Receptor Agonists (Triptans): The vascular 5-HT₁ receptor subtype is present on the human basilar artery and in the vasculature of isolated human dura mater. Current theories on the etiology of migraine headaches suggest that symptoms are caused by local cranial vasodilation or the release of vasoactive and proinflammatory peptides from sensory nerve endings in an activated trigeminal system. The therapeutic activity of the serotonin 5-HT₁ receptor agonists in migraine most likely can be attributed to agonist effects at 5-HT_{1B/1D} receptors on the extracerebral, intracranial blood vessels that become dilated during a migraine attack and on nerve terminals in the trigeminal system. Activation of these receptors results in cranial vessel constriction, inhibition of neuropeptide release, and reduced transmission in trigeminal pain pathways (1).

Regulatory Status

FDA-approved indication: Amerge tablets are indicated for the acute treatment of migraine attacks with or without aura in adults (2).

Limitations of Use: Amerge should be used only if a clear diagnosis of migraine has been established. Amerge tablets are not intended for the prophylactic therapy of migraine or for use

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in the management of hemiplegic or basilar migraine. Safety and effectiveness of Amerge tablets have not been established for cluster headache (2).

This class of medications has potentially serious side effects, especially when taken in high doses. Life-threatening disturbances of cardiac rhythm and myocardial infarction have been reported, as well as stroke. Excessive use of triptans can lead to medication overuse headache. Contraindications include: history of coronary artery disease or coronary artery vasospasm, Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders, history of stroke, transient ischemic attack, or hemiplegic or basilar migraine, peripheral vascular disease, ischemic bowel disease, uncontrolled hypertension, recent (within 24 hours) use of another 5-HT₁ agonist (e.g., another triptan) or an ergotamine-containing medication, hypersensitivity to Amerge (angioedema and anaphylaxis seen), and severe renal or hepatic impairment (2).

Off Label Use:

Triptans have been found to be safe and effective in the pediatric and adolescent population (3).

Related policies

Axert, Butalbital analgesics, Frova, Maxalt, Migraine CGRP Antagonists IV, Migraine CGRP Antagonists SC, Migraine CGRP Antagonists Oral, Migraine Powders, Migranal Nasal Spray, Relpax, Reyvow, Sumatriptan, Sumatriptan Injection, Zomig

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Amerge may be considered **medically necessary** for the treatment of migraine with or without aura (classic or common) and if the conditions indicated below are met.

Amerge may be considered **investigational** for patients below 6 years of age and all other indications.

Prior-Approval Requirements

Age 6 years of age or older
Ages 6-11 must be prescribed by a neurologist

Diagnoses

Patient must have **ONE** of the following:

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1. Migraine, with aura (classic)
2. Migraine, without aura (common)

AND NONE of the following:

- a. Hemiplegic migraine
- b. Basilar migraine
- c. Dual therapy after 6 months of calcitonin gene related peptide (CGRP) antagonist therapy
- d. Dual therapy with Reyvow (lasmiditan)
- e. Another PA on file for any triptan agent

Prior-Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Age 12 years of age or older
 No Pre-PA Allowance for 6-11 years of age

Quantity

Strength	Quantity
1 mg	63 tablets per 90 days OR
2.5 mg	27 tablets per 90 days

Prior - Approval Limits

Quantity

Strength	Quantity
1 mg	90 tablets per 90 days OR
2.5 mg	36 tablets per 90 days

Duration 6 months

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Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

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 migraine. Safety and effectiveness of Amerge tablets have not been established for cluster headache. This class of medications has potentially serious side effects, especially when taken in high doses. Life-threatening disturbances of cardiac rhythm and myocardial infarction have been reported, as well as stroke (2). Triptans have been found to be safe and effective in the pediatric and adolescent population (3).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Amerge while maintaining optimal therapeutic outcomes.

References

1. Serotonin 5-HT₁ Receptor Agonists (Triptans). Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; October 2019. Accessed January 11, 2021.
2. Amerge [package insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2020.
3. Evers S. The Efficacy of Triptans in Childhood and Adolescence Migraine. *Curr Pain Headache Rep.* 2013 July;17(7)342.

Policy History

Date	Action
March 2005	Change in Pre-PA Allowance and Prior – Approval Limits due to manufacturer’s packaging. The drug is pre-packaged in boxes of 9 tablets, and some pharmacies will not split packaging – under the old quantity limits, this resulted in member’s receiving less medication than they were approved for. This adjustment in PA limits sets the quantity limit at two times the pre-PA quantity limits, which is the same ratio as other drugs in this class.
April 2011	Annual editorial review and update
December 2012	Changed quantity limit to 1.5 x FDA-approved dosage Annual editorial review

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April 2013	Revised quantity limits to allow mail order to fill correctly
September 2014	Revision of age to allow pediatric and adolescent use Annual editorial review and reference update
June 2015	Annual editorial review and reference update
March 2016	Annual editorial review and reference update Policy number changed from 5.02.03 to 5.70.03
March 2017	Annual review and reference update
March 2018	Annual editorial review and reference update
November 2018	Annual editorial review and reference update. Addition of no dual therapy with CGRP antagonist requirement and no dual therapy with another PA for any triptan agent
March 2019	Annual review
September 2019	Revised quantity limits to quantity per 90 days
November 2019	Addition of no dual therapy with Reyvow
December 2019	Annual review
March 2020	Annual review and reference update
June 2020	Annual review
March 2021	Annual review and reference update

Keywords

This policy was approved by the FEP[®] Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.