

### Clinical Pharmacy Program Guidelines for Migranal

Program	Prior Authorization
Medication	Migranal (dihydroergotamine mesylate) nasal spray
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	3/2015
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

**1. Background:**

Migranal is indicated for the acute treatment of migraine headaches with or without aura. Migranal Nasal Spray is not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.

**2. Coverage Criteria:**

<p><b>A. <u>Migranal Nasal Spray</u></b></p> <p>1. Diagnosis of migraine headaches with or without aura.</p> <p style="text-align: center;"><b>-AND-</b></p> <p>2. History of failure, contraindication, or intolerance to two preferred 5-HT1 receptor agonist (triptan) alternatives (e.g., sumatriptan or rizatriptan)</p> <p><b>Authorization will be issued for 12 months.</b></p> <p><b>B. <u>Migranal Nasal Spray- Quantity Limit</u></b></p> <p>1. Quantity requests exceeding the limited amount per month for frequently occurring migraines will be approved based on all of the following:</p> <p style="padding-left: 20px;">a. Diagnosis of migraine headaches with or without aura</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 20px;">b. Prescribed by or in consultation with a neurologist or pain management specialist</p> <p style="text-align: center;"><b>-AND-</b></p>
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- c. Currently receiving prophylactic therapy with at least **one** of the following:
- (a) Amitriptyline (Elavil)
  - (b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol \*\*\*NOTE\*\*\* Nadolol and timolol are non-preferred and should not be included in denial to provider
  - (c) Divalproex sodium (Depakote/Depakote ER)
  - (d) OnabotulinumtoxinA (Botox) \*\*\*NOTE\*\*\* This is a medical benefit, should not be included in denial to provider
  - (e) Topiramate (Topamax)
  - (f) Venlafaxine (Effexor/Effexor XR)
  - (g) Calcitonin gene-related peptide (CGRP) receptor antagonists [eg, Aimovig (erenumab), Emgality (galcanezumab)]

**-AND-**

- d. Both of the following:

- (1) One of the following:

- (a) Higher dose or quantity is supported by the manufacturer's prescribing information

**-OR-**

- (b) Higher dose or quantity is supported by one of following compendia:
  - American Hospital Formulary Service Drug Information
  - Thomson Micromedex DrugDex
  - Clinical Pharmacology
  - United States Pharmacopoeia-National Formulary (USP-NF)

**-OR-**

- (c) Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the FDA for the diagnosis indicated.

**-AND-**

(2) Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

**Authorization will be issued for 12 months.**

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**

1. Migranal [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; August 2019.
2. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2012 Apr 24;78(17):1337-45.
3. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016 May 10; 86(19):1818-26.
4. The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. *Headache: The Journal of Head and Face Pain*. 2019;59: 1-18.

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<b>Change Control</b>	
Date	Change
3/2015	New policy
10/2016	Updated quantity limit section to closely align with Triptans quantity limit section. Updated policy template.
11/2017	Updated background. Removed endnotes. Updated references.
2/2018	Removed table from End Notes. Minor update to background.
2/2019	Updated background and references. Updated prophylactic therapy drugs to match CGRP language for episodic migraines.

2/2020	Updated prophylactic therapy drugs in the quantity limit section to match Triptans policy quantity limit section. Updated references.
2/2021	Annual review, updated references.