

Clinical Pharmacy Program Guidelines for Migranal

Program	Prior Authorization
Medication	Migranal (dihydroergotamine mesylate) nasal spray
Markets in Scope	Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, New York EPP, Ohio, Rhode Island
Issue Date	3/2015
Pharmacy and Therapeutics Approval Date	2/2018
Effective Date	4/2018

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>A. <u>Migranal Nasal Spray</u></p> <p>1. Confirmed diagnosis of migraine headaches with or without aura.</p> <p style="text-align: center;">-AND-</p> <p>2. History of failure, contraindication, or intolerance to two formulary 5-HT1 receptor agonist (triptan) alternatives [eg, Imitrex (sumatriptan), Maxalt or Maxalt-MLT (rizatriptan)]</p> <p>Authorization will be issued for 12 months.</p> <p>B. <u>Migranal Nasal Spray- Quantity Limit</u></p> <p>1. Quantity requests exceeding the limited amount per month for frequently occurring migraines will be approved by a clinical pharmacist based on all of the following:</p> <p style="padding-left: 40px;">a. Confirmed diagnosis of migraine headaches with or without aura</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">b. Prescribed by or in consultation with a neurologist or pain management specialist</p>

-AND-

c. Currently receiving prophylactic therapy with at least one of the following agents in patients experiencing two or more headaches monthly:

- Antidepressants [eg, Elavil (amitriptyline)*, Effexor (venlafaxine)]
- Antihistamines (eg, cyproheptadine*)
- Antiepileptics [eg, Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)]
- ACE Inhibitors [eg, Zestril (lisinopril)]
- Angiotensin receptor blockers [eg, Atacand (candesartan)]
- Alpha-agonists (eg, clonidine*, guanfacine*)
- Beta-blockers [eg, Inderal (propranolol), timolol, Toprol XL (metoprolol)]

-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
- Micromedex DRUGDEX[®] System
- Clinical Pharmacology

-OR-

(c) Physician provides evidence to support safety and additional efficacy at higher than maximum doses as documented in published biomedical literature demonstrating safety and efficacy of 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.

NOTES: *Amitriptyline and cyproheptadine are recommended only for patients less than 65 years old.

NOTE TO PRESCRIBER: A common cause of chronic daily headaches is excessive use of the following medications: analgesics (such as acetaminophen or ibuprofen), narcotics, triptans, or ergotamines.

3. References:

1. Migranal Prescribing Information. Valeant Pharmaceuticals, November 2014.
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4. Silberstein S. Practice parameter: evidence-based guidelines for migraine headache. Report of the Quality Standards Subcommittee of the American Academy of Neurology. Available at: <http://www.neurology.org/cgi/reprint/55/6/754.pdf>. Accessed June 29, 2006.
5. Ziegler D, Ford R, Kriegler J, et al. Dihydroergotamine nasal spray for the acute treatment of migraine. *Neurology.* 1994;44:447-53.
6. Dihydroergotamine Nasal Spray Multicenter Investigators. Efficacy, safety, and tolerability of dihydroergotamine nasal spray as monotherapy in the treatment of acute migraine. *Headache.* 1995;35:177-84.
7. Gallagher RM. Acute treatment of migraine with dihydroergotamine nasal spray. Dihydroergotamine Working Group. *Arch Neurol.* 1996;53:1285-91.
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10. British Association for the Study of Headache (BASH). Guidelines for all healthcare professionals in the diagnosis and management of migraine, tension-type, cluster, and medication over-use headache. January 2010. Available at: http://217.174.249.183/upload/NS_BASH/2010_BASH_Guidelines.pdf. Accessed May 27, 2011.

11. The National Committee for Quality Assurance (NCQA). Use of high-risk medications in the elderly (DAE). Available at www.ncqa.org. Accessed May 26, 2011.
12. Fick DM, Cooper JW, Wade WE, Waller JL, Maclean R, Beers MH. Updating the Beers criteria for potentially inappropriate medication use in older adults. *Arch Intern Med.* 2003;163:2716-2724.

Program	Prior Authorization - Migranal (dihydroergotamine mesylate) nasal spray
Change Control	
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.