

Pharmacy Policy Bulletin

Title: Dihydroergotamine Nasal (Migranal®)

Policy #: Rx.01.205

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▸ Intent:

The intent of this policy is to communicate the medical necessity criteria for dihydroergotamine nasal (Migranal®) as provided under the member's prescription drug benefit.

▸ Description:

Migraines are a type of headache disorder that is associated with moderate to severe pain affecting one side of the head. The pain is described as pulsating or throbbing, and can be associated with photophobia and phonophobia, lasting several hours to days. Some people know when they will get a migraine, experiencing a prodrome 1 or 2 days prior to their migraine onset. Migraines can be associated with aura or without aura, which could be a mix of positive or negative features that are completely reversible. Positive features could be seeing lines or shapes and hearing noises, while negative features could be the loss of vision, hearing, or feeling. Medications can be used prophylactically or as abortive therapy.

Dihydroergotamine (Migranal®) is ergotamine hydrogenated in the 9, 10 position as the mesylate salt. Dihydroergotamine binds with high affinity to 5-HT_{1Dα} and 5-HT_{1Dβ} receptors. The therapeutic activity of dihydroergotamine in migraine is generally attributed to the agonist effect at 5-HT_{1D} receptors. Two current theories have been proposed to explain the efficacy of 5-HT_{1D} receptor agonists in migraine. One theory suggests that activation of 5-HT_{1D} receptors located on intracranial blood vessels, including those on arterio-venous anastomoses, leads to vasoconstriction, which correlates with the relief of migraine headache. The alternative hypothesis suggests that activation of 5-HT_{1D} receptors on sensory nerve endings of the trigeminal system results in the inhibition of pro-inflammatory neuropeptide release. In addition, dihydroergotamine possesses oxytocic properties.

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

▸ Policy:

Dihydroergotamine mesylate (Migranal®) is approved when BOTH of the following are met:

1. Diagnosis of moderate to severe migraine headache with or without aura; and
2. Inadequate response or inability to tolerate TWO oral and nasal triptans

▾ **Black Box Warning as shown in the drug Prescribing Information:**

Serious and/or life-threatening peripheral ischemia has been associated with the coadministration of dihydroergotamine with potent CYP 3A4 inhibitors including protease inhibitors and macrolide antibiotics. Because CYP 3A4 inhibition elevates the serum levels of dihydroergotamine, the risk for vasospasm leading to cerebral ischemia and/or ischemia of the extremities is increased. Hence, concomitant use of these medications is contraindicated.

▾ **Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION


Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▾ **References:**

Cutrer MF and Bajwa ZH. Pathophysiology, clinical manifestations, and diagnosis of migraine in adults. UpToDate. Accessed January 23, 2019.

Migranal® (dihydroergotamine mesylate) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; August 2017. Available at: <http://valeant.com/Portals/25/Pdf/PI/Migranal-PI.pdf>. Accessed January 28, 2019.

▾ **Applicable Drugs:**

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Migranal®	Dihydroergotamine mesylate

▾ **Cross References:**

N/A

Policy Version Number:	2.00
P&T Approval Date:	January 10, 2019
Policy Effective Date:	April 01, 2019
Next Required Review Date:	January 10, 2020

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.