

Title: dihydroergotamine mesylate (DHE 45) injectable

Origination: 03/14/06	Revised: 11/11/11	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Dihydroergotamine (DHE 45) is a medication that binds with high affinity to the 5HT_{1D} receptors, which leads to vasoconstriction, and therefore the relief of migraine headaches. DHE 45 is indicated for the acute treatment of migraine headaches with or without aura. DHE 45 is also indicated for the acute treatment of cluster headache episodes.
- Dihydroergotamine (DHE 45) solution can be administered orally, intramuscularly, subcutaneously, and intravenously.

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

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Background Information, continued:

Exclusions

- Members less than 18 years of age, as safety and efficacy have not been established.
- Concomitant use with potent CYP3A4 inhibitors (including but not limited to numerous anti-retroviral agents for HIV - amprenavir, atazanavir, ritonavir, nelfinavir, indinavir, saquinavir, delavirdine, efavirenz; and erythromycin, clarithromycin, ketoconazole, and itraconazole).
- Member with history, signs, or symptoms of ischemic cardiac syndromes (including but not limited to, angina pectoris of any type, all forms of myocardial infarction, and silent myocardial ischemia), cerebrovascular syndromes (including but not limited to, strokes of any kind and transient ischemic attacks), peripheral vascular symptoms (including but not limited to, ischemic bowel disease), or other significant underlying cardiovascular diseases
- Member with uncontrolled hypertension.
- Concomitant use with other ergotamine-containing or ergot-type medications or methysergide within 24 hours of one another.
- Member with documented peripheral vascular disease, sepsis, or following vascular surgery
- Member with hemiplegic or basilar migraine.
- Member with severely impaired hepatic or renal function.
- Member who is pregnant or nursing.
- Member with hypersensitivity to ergot alkaloids.

Procedure:

- 1.0 Request for *initial therapy* for **migraine and cluster headaches** require documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
 - 1.1 Diagnosis of Migraine headaches or Cluster headaches, **AND**
 - 1.2 Migraine not controlled with oral migraine medications, **OR**
 - 1.2 Member cannot tolerate oral migraine medications, **OR**
 - 1.2 Injection needed due to Member experiencing nausea/vomiting associated with migraine attacks.
- 2.0 If criteria have been met, initial therapy may be approved for up to 24ml (24mg) per month for a maximum of three (3) months.

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Procedure, continued:

- 3.0 Request for *continuation of therapy* for **migraine and cluster headaches** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the Member is not experiencing any severe adverse reactions:
- 3.1 If criterion is met, continuation of therapy may be approved for up to 24ml (24mg) per month for a maximum of one (1) year.

References:

1. D.H.E.45 (dihydroergotamine mesylate injection) Full Prescribing Information. Novartis Pharmaceuticals. Stein, Switzerland. Revised 11/2007.
2. Evers, S, Afra, J, Frese, A, Goadsby, PJ, Linde, M, May, A, Sandor, PS. *EFNS Guidelines on the drug treatment of migraine*. Eur J Neurol. 2006 Jun;13(6):560-72.
3. Landy S, Smith T. Treatment of primary headache: acute migraine treatment. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 27-39.
4. Medical Letter. Drugs for Migraine, Treatment Guidelines. New Rochelle, NY. 2008 March; 6(67): 17-22. <http://www.medletter.com/downloads/t67.pdf>. Accessed October 8, 2009.
5. Biondi D, Mendes P. Treatment of primary headache: cluster headache. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 59-72.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.