

# Medical Drug Clinical Criteria

<b>Subject:</b>	Dihydroergotamine (DHE) injection		
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## Table of Contents

[Overview](#)

[Coding](#)

[References](#)

[Clinical criteria](#)

[Document history](#)

## Overview

This document addresses the use of dihydroergotamine (DHE) injection. DHE is approved for the subcutaneous, intravenous, or intramuscular treatment of acute migraine headaches with or without aura and the acute treatment of cluster headache episodes.

DHE has a black box warning regarding serious and/or life-threatening peripheral ischemia if co-administered with a potent CYP3A4 inhibitor, including protease inhibitors and macrolide antibiotics. Concomitant use is contraindicated.

## Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

### Dihydroergotamine (DHE) Injection

Requests for intravenous, intramuscular or subcutaneous dihydroergotamine (DHE) injection may be approved if the following criteria are met:

- I. Individual is age 18 or older; **AND**
  - II. Individual is using for acute treatment of migraine with aura; **AND**
  - III. Individual meets the following International Headache Society (IHS) diagnostic criteria (ICHD-3):
    - A. Individual has 2 or more headache attacks; **AND**
    - B. Individual has 1 or more of the following fully reversible aura symptoms:
      1. Visual (for example, flickering lights, spots or lines); **OR**
      2. Sensory (for example, pins and needles, numbness); **OR**
      3. Speech and/or language (for example, aphasia); **OR**
      4. Motor (for example, weakness); **OR**
      5. Brainstem (for example, ataxia or vertigo); **OR**
      6. Retinal (for example, blindness); **AND**
    - C. Individual has at least three of the following six characteristics:
      1. At least 1 aura symptom develops gradually over 5 or more minutes; **OR**
      2. Two (2) or more aura symptoms occur in succession; **OR**
      3. Each individual aura symptom lasts 5 to 60 minutes; **OR**
      4. At least 1 aura symptom is unilateral; **OR**
      5. At least one aura symptom is positive (scintillations and pins and needles are examples of positive symptoms of aura); **OR**
      6. The aura is accompanied, or followed within 60 minutes, by headache; **AND**
    - D. Individual's headache is not attributed to another disorder (for example, ischemia stroke or transient ischemic attack);
- OR**
- IV. Individual is age 18 or older; **AND**
  - V. Individual is using for acute treatment of migraine without aura meeting the following IHS diagnostic criteria (ICHD-3):
    - A. Individual has 5 or more headache attacks; **AND**
    - B. Individual's headaches last 4 to 72 hours (untreated or unsuccessfully treated); **AND**
    - C. Individual's headache has 2 or more of the following characteristics:
      1. Unilateral location; **OR**

- 2. Pulsating quality; **OR**
- 3. Moderate or severe pain intensity; **OR**
- D. Aggravation by or causing avoidance of routine physical activity (for example, walking or climbing stairs); **AND**
- E. Individual's headache is accompanied by 1 or more of the following:
  - 1. Nausea, vomiting or both; **OR**
  - 2. Photophobia or phonophobia; **AND**
- F. Individual's headache is not attributed to another headache disorder;

**OR**

- VI. Individual is age 18 or older; **AND**
- VII. Individual is using for acute treatment of cluster headache episodes meeting the following IHS diagnostic criteria (ICHD-3):
  - A. Individual has 5 or more headache attacks; **AND**
  - B. Individual has severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes if untreated; **AND**
  - C. Individual's headache is accompanied by 1 or both of the following:
    - 1. 1 or more of the following symptoms or signs, ipsilateral to the headache:
      - a. Conjunctival injection and/or lacrimation; **OR**
      - b. Nasal congestion and/or rhinorrhea; **OR**
      - c. Eyelid edema; **OR**
      - d. Forehead and facial sweating; **OR**
      - e. Miosis and/or ptosis; **OR**
    - 2. A sense of restlessness or agitation; **AND**
  - D. Attacks have a frequency from 1 every other day to 8 per day for more than half of the time the disorder is active; and
  - E. Individual's headache is not attributed to another headache disorder.

**OR**

- VIII. Individual has status migrainosus or rebound withdrawal type of headaches.

Requests for intravenous, intramuscular or subcutaneous dihydroergotamine (DHE) injection may not be approved if the following criteria met:

- I. Individual is using concomitantly with a potent CYP3A4 inhibitor (including ritonavir, nelfinavir, idinavir, erythromycin, clarithromycin, troleandomycin, ketoconazole, itraconazole); **OR**
- II. Individual has a diagnosis of ischemic heart disease (angina pectoris, history of myocardial infarction, documented silent ischemia) or has clinical symptoms consistent with coronary artery vasospasm including Prinzmetal's variant angina; **OR**
- III. Individual has uncontrolled hypertension; **OR**
- IV. Individual has hemiplegic or basilar migraine; **OR**
- V. Individual has used a 5-HT1 agonist (such as sumatriptan), ergotamine-containing or ergot-type medication or methysergide within the previous 24 hours; **OR**
- VI. Individual has peripheral arterial disease; **OR**
- VII. Individual has severely impaired hepatic or renal function.

## Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

### HCPCS

J1110 Injection, dihydroergotamine mesylate, per 1 mg

### ICD-10 Diagnosis

G43.001-G43.919 Migraine  
 G44.001-G44.029 Cluster headaches  
 G44.40-G44.41 Drug-induced headache not elsewhere classified

## Document History

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Document History:

- 05/17/2024 – Annual Review: No changes. Coding Reviewed: No changes.

- 05/19/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/20/2022 – Annual Review: Update may not approve section to include all contraindications; remove flushing from diagnostic criteria for cluster headache for consistency. Coding Reviewed: No changes.
- 05/21/2021 – Annual Review: Updated prior authorization to remove allowance as an alternative to narcotic therapy for migraine or cluster headaches as diagnosis alone would allow for approval; removed allowance for those unresponsive to triptans as step therapy has same requirement. Coding Reviewed: No changes.
- 05/15/2020 – Annual Review: No changes. Coding reviewed: No changes.
- 05/17/2019 – Annual Review: Removed nasal spray from dihydroergotamine step therapy to create dihydroergotamine injection step therapy, minor wording and formatting updates to potential preferred agents, added Tosymra as a potential preferred triptan. Coding reviewed: no changes
- 11/16/2018 –Select Review: Initial P&T review for Dihydroergotamine (DHE) Injection. Updated criteria based on ICHD-3 diagnostic criteria for migraine headaches. Updated to include intramuscular administration as allowed per label. Added may not be approved criteria based on labeled contraindications. Proposed new quantity limit based on labeled maximum dose of 6 mL per week. HCPCS and ICD-10 coding review: no changes.

## References

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3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3<sup>rd</sup> edition. *Cephalalgia*. 2018; 38(1):1-211. Available from: <https://www.ichd-3.org/wp-content/uploads/2018/01/The-International-Classification-of-Headache-Disorders-3rd-Edition-2018.pdf>.
5. Robbins MS, Starling AJ, Pringsheim TM, Becker WJ, Schwedt TJ. Treatment of cluster headache: The American Headache Society evidence-based guidelines. *Headache*. 2016;56:1093-1106.

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