Dihydroergotamine Mesylate (DHE)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Dihydroergotamine Mesylate (DHE) injection	May be subject to quantity limit

APPROVAL CRITERIA

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

I. Individual is requesting for treatment of acute migraine with or without aura; **AND**
II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to two preferred triptan agents.

Preferred agents: Almotriptan tablets (not in CA, CO), eletriptan (generic Relpax) tablets (not in CA, CO), naratriptan (generic Amerge) tablets, rizatriptan/rizatriptan ODT (generic Maxalt/Maxalt-MLT), sumatriptan (generic Imitrex) tablets/nasal spray (not in CA, CO, CT)/injection, zolmitriptan/zolmitriptan ODT (generic Zomig/Zomig ZMT) (not in CA, CO) tablets

OR

III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to sumatriptan nasal spray or injection; **AND**
IV. Oral triptan agents are not acceptable due to concomitant clinical conditions, such as but not limited to the following:
    a. Individual is unable to take oral medications due to one of the following:
        i. Individual experiences nausea and vomiting due to migraines; **OR**
        ii. Individual requires a more rapid onset of action due to short aura time period; **OR**
        iii. Individual cannot swallow tablets and there are no preferred ODT (oral disintegrating tablet) formulations;

OR

V. Individual is requesting for acute treatment of cluster headache; **AND**
VI. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one of the following agents for treatment of cluster headaches (AHS 2016):
    A. Sumatriptan (subcutaneous or nasal spray (nasal spray not in CA, CO, CT)); **OR**
    B. Zolmitriptan (oral) (not in CA, CO);

OR

VII. Individual is requesting for status migrainosus or rebound withdrawal type of headaches;

AND

VIII. Individual is age 18 or older; **AND**

IX. Individual is using for acute treatment of migraine with aura; **AND**

X. 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

XI. Individual is age 18 or older; **AND**

XII. 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 to72 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**
4. Aggravation by or causing avoidance of routine physical activity (for example, walking or climbing stairs);

AND

D. Individual's headache is accompanied by 1 or more of the following:

1. Nausea, vomiting or both; **OR**
2. Photophobia or phonophobia;

AND

E. Individual's headache is not attributed to another headache disorder.

OR

XIII. Individual is age 18 or older; **AND**

XIV. 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. One (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. Forehead and facial flushing; **OR**
    f. 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

XV. Individual has status migrainosis 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.

Note: 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.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 13, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd 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. Accessed: April 13, 2021.