

Market Applicability													
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

## Dihydroergotamine Mesylate (DHE)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Dihydroergotamine Mesylate (DHE) injection

### APPROVAL CRITERIA

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

- I. 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: sumatriptan tablet, naratriptan tablet

### **AND**

- II. Individual is age 18 or older; **AND**
- III. Individual is using for acute treatment of migraine with aura; **AND**
- IV. 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**

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0396-19

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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**

- V. Individual is age 18 or older; **AND**
- VI. 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**
    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**

- VII. Individual is age 18 or older; **AND**
- VIII. Individual is using for acute treatment of cluster headache episodes in an adult 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:

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- 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**

- IX. Individual has status migrainosis or rebound withdrawal type of headaches;

**OR**

- X. Individual has only received narcotics for severe migraine or cluster headaches;

**OR**

- XI. Individual is unresponsive to prior use of triptans for severe migraine or cluster headache.

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-HT<sub>1</sub> 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**

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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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. 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: October 4, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. 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>. Accessed: October 4, 2018.

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