

## PHARMACY COVERAGE GUIDELINE

**Dihydroergotamine mesylate injection (1 mg/mL)**

**Dihydroergotamine mesylate nasal spray (0.5 mg/spray)**

**MIGRANAL® (dihydroergotamine mesylate) nasal spray (0.5 mg/spray)**

**TRUDHESA™ (dihydroergotamine mesylate) nasal spray (0.725 mg/spray)**

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### **This Pharmacy Coverage Guideline (PCG):**

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

### **Scope**

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

### **Instructions & Guidance**

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy). You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com).

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### **Criteria:**

#### **Section A. Moderate to severe acute migraine headache with or without aura:**

**Dihydroergotamine mesylate injection**

**Dihydroergotamine mesylate nasal spray**

**MIGRANAL (dihydroergotamine mesylate) nasal spray**

**TRUDHESA (dihydroergotamine mesylate) nasal spray**

- **Criteria for initial therapy:** Generic dihydroergotamine mesylate nasal spray, Migranal (dihydroergotamine mesylate) nasal spray, Trudhesa (dihydroergotamine mesylate) nasal spray, or generic dihydroergotamine

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mesylate injection is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is **ONE** of the following:
  - a. A Neurologist
  - b. A licensed professional authorized by his or her license to prescribe dihydroergotamine mesylate **and ONE** of the following:
    - i. Is prescribing in consultation with a Neurologist or Pain Specialist
    - ii. Is certified as a headache specialist by the United Council for Neurologic Subspecialties (UCNS)
    - iii. Has earned a Certificate in Added Qualifications (CAQ) in Headache Medicine from the National Headache Foundation
2. Individual is between 18-65 years of age
3. Individual has a confirmed diagnosis of **acute moderate to severe migraine headaches with or without aura**
4. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for **TWO abortive agents** (one agent from each of the following category of preferred step therapy):
  - a. NSAIDs: aspirin 500 mg, diclofenac 50 mg, ibuprofen 400 mg or naproxen 500 mg
  - b. Triptans: naratriptan, rizatriptan, sumatriptan, and zolmitriptan
5. **Additional criteria for Migranal (dihydroergotamine mesylate) nasal spray only:** Individual has failure, contraindication, intolerance, or is not a candidate for **BOTH** generic dihydroergotamine mesylate nasal spray and Trudhesa (dihydroergotamine mesylate) nasal spray
6. Individual uses and is adherent with **ONE** of the following migraine prophylactic medications:
  - a. Beta-blocker such as metoprolol, propranolol, or timolol
  - b. Antidepressant such as amitriptyline or venlafaxine
  - c. Anticonvulsant such as valproate, divalproex, or topiramate
7. Individual has failure, contraindication, intolerance, or is not a candidate for a preventive calcitonin gene-related peptide receptor antagonist (CGRP) e.g., Aimovig, Ajovy, Emgality, Nurtec, etc.
8. There are **NO** FDA-label contraindications such as:
  - a. Concurrent use with potent CYP450 3A4 inhibitor (e.g., ritonavir, erythromycin, clarithromycin, ketoconazole, itraconazole, others)
  - b. Ischemic heart disease (angina pectoris, history of myocardial infarction, or documented silent ischemia)
  - c. Coronary artery vasospasm, including Prinzmetal's variant angina
  - d. Uncontrolled hypertension
  - e. Hemiplegic or basilar migraine
  - f. Concurrent use (within 24 hours) with 5HT1 agonists (sumatriptan, naratriptan, zolmitriptan, etc.), ergotamine-containing or other ergot-type medications or methysergide

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- g. Known peripheral arterial disease
- h. Use following vascular surgery
- i. Sepsis
- j. Severe hepatic impairment
- k. Severe renal impairment
- l. Pregnancy in an individual of childbearing age
- m. Individual who is nursing an infant or child
- n. Previous hypersensitivity to ergot alkaloids
- o. Concurrent use with peripheral and central vasoconstrictors

**Initial approval duration:** 6 months

➤ **Criteria for continuation of coverage (renewal request):** Generic dihydroergotamine mesylate nasal spray, Migranal (dihydroergotamine mesylate) nasal spray, Trudhesa (dihydroergotamine mesylate) nasal spray, or generic dihydroergotamine mesylate injection is considered **medically necessary** and will be approved when **ALL** of the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual continues to be seen by **ONE** of the following:
  - a. Neurologist
  - b. A licensed professional authorized by his or her license to prescribe dihydroergotamine mesylate **and ONE** of the following:
    - i. Is prescribing in consultation with a Neurologist or Pain Specialist
    - ii. Is certified as a headache specialist by the UCNS
    - iii. Has earned a CAQ in Headache Medicine from the National Headache Foundation
2. Individual's condition has responded while on therapy with response defined as **ALL** of the following:
  - a. At least a 50% reduction in the number of migraine days per month from baseline
  - b. A reduction in the number of days of use of acute migraine-specific medications from baseline
  - c. Reduction in emergency visits for acute migraine treatment
3. Individual has been adherent with the medication
4. **Additional criteria for Migranal (dihydroergotamine mesylate) nasal spray only:** Individual has failure, contraindication, intolerance, or is not a candidate for generic dihydroergotamine mesylate nasal spray
5. Uses at least one migraine prevention/prophylactic agent
6. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use as follows:
  - a. Contraindications as listed in the criteria for initial therapy section
  - b. Significant adverse effect such as:
    - i. Pleural and retroperitoneal fibrosis
    - ii. Cardiac valvular fibrosis

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- iii. Acute myocardial infarction
- iv. Life-threatening cardiac dysrhythmia
- v. Cerebral hemorrhage, subarachnoid hemorrhage, stroke, or transient ischemic attack
- vi. Any vasospastic phenomenon
- vii. Ischemic bowel
- viii. Raynaud's syndrome
- ix. Ergotism

**Renewal duration:** 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

### **Section B. Acute cluster headache episodes:**

#### **Dihydroergotamine mesylate injection**

- **Criteria for initial therapy:** Generic dihydroergotamine mesylate injection is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
  1. Prescriber is **ONE** of the following:
    - a. A Neurologist
    - b. A licensed professional authorized by his or her license to prescribe Emgality **and ONE** of the following:
      - i. Is prescribing in consultation with a Neurologist or Pain Specialist
      - ii. Is certified as a headache specialist by the United Council for Neurologic Subspecialties (UCNS)
      - iii. Has earned a Certificate in Added Qualifications (CAQ) in Headache Medicine from the National Headache Foundation
  2. Individual is between 18-65 years of age
  3. Individual has a confirmed diagnosis of **acute cluster headache episodes** according to International Headache Society (IHS) International Classification of Headache Disorders (ICHD).
  4. Use of **EITHER** oxygen or sumatriptan (subcutaneous or intranasal) or intranasal zolmitriptan for acute episodes of cluster headache is suboptimal

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5. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following preventative cluster headache agents where the dose has been stable for at least 2 months (60 days):
  - a. Verapamil
  - b. Prednisone or dexamethasone
  - c. Topiramate
  - d. Lithium carbonate
6. There are **NO** FDA-label contraindications such as:
  - a. Concurrent use with potent CYP450 3A4 inhibitor
  - b. Ischemic heart disease (angina pectoris, history of myocardial infarction, or documented silent ischemia)
  - c. Coronary artery vasospasm, including Prinzmetal's variant angina
  - d. Uncontrolled hypertension
  - e. Hemiplegic or basilar migraine
  - f. Concurrent use (within 24 hours) with 5HT<sub>1</sub> agonists (sumatriptan, naratriptan, zolmitriptan, etc.), ergotamine-containing or other ergot-type medications or methysergide
  - g. Known peripheral arterial disease
  - h. Following vascular surgery
  - i. Sepsis
  - j. Severe hepatic impairment
  - k. Severe renal impairment
  - l. Pregnancy
  - m. Woman who is nursing an infant or child
  - n. Previous hypersensitivity to ergot alkaloids
  - o. Concurrent use with peripheral and central vasoconstrictors

**Initial approval duration:** 6 months

➤ **Criteria for continuation of coverage (renewal request):** Generic dihydroergotamine mesylate injection is considered **medically necessary** and will be approved when **ALL** of the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual continues to be seen by **ONE** of the following:
  - a. Neurologist
  - b. A licensed professional authorized by his or her license to prescribe Emgality **and ONE** of the following:
    - i. Is prescribing in consultation with a Neurologist or Pain Specialist
    - ii. Is certified as a headache specialist by the UCNS
    - iii. Has earned a CAQ in Headache Medicine from the National Headache Foundation
2. Individual's condition has responded while on therapy with response defined as **TWO** of the following:
  - a. A reduction in the weekly cluster headache attack frequency from baseline
  - b. At least a 50% reduction in the weekly cluster headache frequency from baseline

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- c. No emergency room or urgent care visits for acute treatment
- 3. Individual has been adherent with the medication
- 4. Individual uses at least one prevention/prophylactic agent
- 5. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use as follows:
  - a. Contraindications as listed in the criteria for initial therapy section
  - b. Significant adverse effect such as:
    - i. Pleural and retroperitoneal fibrosis
    - ii. Cardiac valvular fibrosis
    - iii. Acute myocardial infarction
    - iv. Life-threatening cardiac dysrhythmia
    - v. Cerebral hemorrhage, subarachnoid hemorrhage, stroke, or transient ischemic attack
    - vi. Any vasospastic phenomenon
    - vii. Ischemic bowel
    - viii. Raynaud's syndrome
    - ix. Ergotism

**Renewal duration:** 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:
  - 1. **Off-Label Use of Non-Cancer Medications**
  - 2. **Off-Label Use of Cancer Medications**

### **Description:**

Migranal (dihydroergotamine mesylate) nasal spray, Trudhesa (dihydroergotamine mesylate) nasal spray, generic dihydroergotamine mesylate nasal spray, or generic dihydroergotamine mesylate injection is indicated for the acute treatment of migraine headaches with or without aura. Migranal (dihydroergotamine mesylate) nasal spray, Trudhesa (dihydroergotamine mesylate) nasal spray, generic dihydroergotamine mesylate nasal spray, or generic dihydroergotamine mesylate injection is not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine. Migranal (dihydroergotamine mesylate) nasal spray, Trudhesa (dihydroergotamine mesylate) nasal spray, generic dihydroergotamine mesylate nasal spray, or generic dihydroergotamine mesylate injection should only be used where a clear diagnosis of migraine headache has been established.

Generic dihydroergotamine mesylate injection is also indicated for the acute treatment of cluster headache episodes.

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Dihydroergotamine binds with high affinity to 5-HT<sub>1D</sub> $\alpha$  and 5-HT<sub>1D</sub> $\beta$  receptors. It also binds with high affinity to serotonin 5-HT<sub>1A</sub>, 5-HT<sub>2A</sub>, and 5-HT<sub>2C</sub> receptors, noradrenaline  $\alpha$ <sub>2A</sub>,  $\alpha$ <sub>2B</sub> and  $\alpha$ <sub>1</sub> receptors, and dopamine D<sub>2L</sub> and D<sub>3</sub> receptors. The therapeutic activity of dihydroergotamine in migraine is generally attributed to the agonist effect at 5-HT<sub>1D</sub> receptors. Two current theories have been proposed to explain the efficacy of 5-HT<sub>1D</sub> receptor agonists in migraine. One theory suggests that activation of 5-HT<sub>1D</sub> 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<sub>1D</sub> receptors on sensory nerve endings of the trigeminal system results in the inhibition of pro-inflammatory neuropeptide release. In addition, dihydroergotamine possesses oxytocic properties.

Migraine is a common episodic disorder, the hallmark of which is a disabling headache generally associated with nausea, and/or light and sound sensitivity. Migraine with aura refers to the occurrence of transient visual, sensory, language, or motor disturbance that is followed by a migraine headache. The exact mechanisms of migraine are unknown, but currently it is believed to initiate from a primary neuronal dysfunction that leads to a sequence of intracranial and extracranial changes accounting for migraine, including the four phases of premonitory symptoms, aura, headache and post-drome. Specifically, activation of the trigeminovascular system, cortical spreading depression, and neuronal sensitization all seem to play a role.

Selection of medication for acute treatment is directed by the severity of the attacks, presence of associated nausea and vomiting, treatment setting, and patient-specific factors. Abortive treatments are usually more effective if they are given early during the headache (within in the first hour if possible). The 2015 updated guideline assessment published by the American Headache Society lists the following medications as Level A (established as effective) for acute migraine treatment: all triptan drugs, NSAIDs (naproxen, ibuprofen, aspirin, diclofenac), combination of sumatriptan and naproxen, acetaminophen/aspirin/caffeine, acetaminophen (for acute treatment of non-incapacitating migraine), and dihydroergotamine nasal spray.

Prophylactic headache treatment is indicated if the headaches are frequent, long lasting, or account for a significant amount of total disability. Several drug classes are used for the prevention of migraine. Medications that are effective in controlled trials include: beta blockers (metoprolol, propranolol, and timolol); anticonvulsants (valproate, divalproex, and topiramate); and antidepressants (amitriptyline and venlafaxine).

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### **Definitions:**

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting  
[MedWatch Forms for FDA Safety Reporting | FDA](#)

### **Cluster headache:**

- The most common type of Trigeminal Autonomic Cephalalgias (TAC)
- Attacks of severe orbital, supraorbital, or temporal pain, accompanied by autonomic phenomena and/or restless or agitation
- Unilateral autonomic symptoms associated with cluster headache include ptosis, miosis, lacrimation, conjunctival injection, rhinorrhea, and nasal congestion, occur only during the pain attack and are ipsilateral to the pain
- The attacks may strike up to eight times a day and are relatively short-lived (usually 15-180 minutes)

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### Dihydroergotamine mesylate nasal spray (0.5 mg/spray)

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- The headache is strictly unilateral; the symptoms remain on the same side of the head during a single cluster attack
- The symptoms can switch to the other side during a different cluster attack (so-called side shift) in approximately 15% of cases
- In contrast to migraine, patients with cluster are restless and prefer to pace about or sit and rock back and forth

#### Diagnostic criteria for cluster headache:

<b>Cluster headache:</b> Diagnostic criteria for cluster headache require the following:
A. At least <b>five attacks</b> fulfilling criteria B through D
B. Severe or very severe <b>unilateral</b> orbital, supraorbital, and/or temporal pain lasting 15-180 minutes when untreated; during part (but less than half) of the active time course of cluster headache, attacks may be less severe and/or of shorter or longer duration
C. <b>Either or both</b> of the following:
1. At least <b>one</b> of the following symptoms or signs ipsilateral to the headache:
a) Conjunctival injection and/or lacrimation
b) Nasal congestion and/or rhinorrhea
c) Eyelid edema
d) Forehead and facial sweating
e) Miosis and/or ptosis
2. A sense of restlessness or agitation
D. Attacks have a frequency between one every other day and eight per day; during part (but less than half) of the active time-course of cluster headache, attacks may be less frequent
E. Not better accounted for by another ICHD-3 diagnosis
<b>Episodic cluster headache:</b> Diagnostic criteria for episodic cluster headache require the following:
A. Attacks fulfilling criteria for cluster headache and occurring in bouts (cluster periods)
B. At least two cluster periods lasting from seven days to one year (when untreated) and separated by pain-free remission periods of three months or more
<b>Chronic cluster headache:</b> Diagnostic criteria for chronic cluster headache require the following:
A. Attacks fulfilling criteria for cluster headache
B. Attacks occurring without a remission period, or with remissions lasting less than three months, for at least one year

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*Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition. Cephalalgia 2018; 38:1.*

Identification of headache type: migraine, tension, or cluster			
	Migraine	Tension	Cluster
Location	Unilateral	Bilateral	Supraorbital/temporal
Pain intensity <sup>1</sup>	Moderate to severe	Mild to moderate	Severe
Duration	4–72 hours	30 minutes to 7 days	15–180 minutes
Characterization of pain	Pulsing	Pressure/squeezing	Boring/stabbing
Sensitivity to light/sound	One or both may be present	Both are absent or only one is present	No
Nausea/vomiting	One or both may be present	No	One or both may be present
Aggravated by routine activity	Yes	No	No
Aura	May be present	No	No
Associated symptoms	None	None	Miosis, ptosis, rhinorrhea
<sup>1</sup> Pain intensity <ul style="list-style-type: none"> <li>Mild—Patient is aware of a headache but is able to continue daily routine with minimum alterations.</li> <li>Moderate—The headache inhibits daily activities; migraine pain is more noticeable but is not incapacitating.</li> <li>Severe—The headache is incapacitating such that patient is no longer able to engage in normal activities.</li> </ul>			

### Resources:

D.H.E. 45 (dihydroergotamine mesylate) injection product information, revised by Bausch Health US, LLC. 11-2019. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed September 06, 2022. **Discontinued 06-10-2022.**

Dihydroergotamine mesylate injection product information, revised by Hikma Pharmaceuticals USA, Inc 05-2022. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed August 21, 2024.

Migranal (dihydroergotamine mesylate) nasal spray product information, revised by Bausch Health US, LLC. 09-2022. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed August 21, 2024.

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Trudhesa (dihydroergotamine mesylate) nasal spray product information, revised by Impel, Inc. 08-2023. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed August 21, 2024.

Schwedt TJ, Garza I. Acute treatment of migraine in adults. In: UpToDate, Swanson JW, Goddeau RP (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through July 2024. Topic last updated July 22, 2024. Accessed August 21, 2024.

Schwedt TJ, Garza I. Preventive treatment of episodic migraine in adults. In: UpToDate, Swanson JW, Goddeau RP (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through July 2024. Topic last updated July 22, 2024. Accessed August 21, 2024.

Garza I, Schwedt TJ. Chronic migraine. In: UpToDate, Swanson JW, Robertson CE, Goddeau RP (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through July 2024. Topic last updated June 04, 2024. Accessed August 21, 2024.

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