PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

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ARCHIVE DATE:

D.H.E. 45 (dihydroergotamine mesylate) injection 1 mg/mL
Dihydroergotamine Mesylate injection 1 mg/mL
Dihydroergotamine Mesylate nasal spray 4 mg/mL
MIGRANAL® (dihydroergotamine mesylate) nasal spray 4 mg/mL
TRUDHESA™ (dihydroergotamine mesylate) nasal spray 4 mg/mL

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the

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form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Section A. Moderate to severe acute migraine headache with or without aura:
D.H.E. 45 (dihydroergotamine mesylate) injection
Dihydroergotamine mesylate injection AND nasal spray
MIGRANAL (dihydroergotamine mesylate) nasal spray
TRUDHESA (dihydroergotamine mesylate) nasal spray

Criteria:

- **Criteria for initial therapy**: Generic dihydroergotamine mesylate nasal spray, Migranal (dihydroergotamine mesylate) nasal spray, Trudhesa (dihydroergotamine mesylate) nasal spray, D.H,E 45 (dihydroergotamine mesylate) injection, or 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 Migranal (dihydroergotamine mesylate) nasal spray, generic Dihydroergotamine mesylate nasal spray or generic Dihydroergotamine mesylate injection **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. A confirmed diagnosis of acute moderate to severe migraine headaches with or without aura

  4. Individual has failure, contraindication per FDA label, or intolerance to **TWO** abortive agents 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

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5. **Additional criteria for dihydroergotamine mesylate injection (D.H.E. 45 or generic) only**:
    a. Individual has failure, contraindication, or intolerance to **BOTH** Migranal (dihydroergotamine mesylate) nasal spray and generic dihydroergotamine mesylate nasal spray

6. 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, or intolerance to **EITHER** Aimovig (erenumab-aooe) or Emgality (galcanezumab)

8. 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 5HT1 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

9. There are no significant interacting drugs

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, D.H.E. 45 (dihydroergotamine mesylate) injection, or generic dihydroergotamine mesylate injection is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

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Dihydroergotamine Mesylate injection 1 mg/mL
Dihydroergotamine Mesylate nasal spray 4 mg/mL
MIGRANAL® (dihydroergotamine mesylate) nasal spray 4 mg/mL
TRUDHESA™ (dihydroergotamine mesylate) nasal spray 4 mg/mL

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 Migranal (dihydroergotamine mesylate), generic Dihydroergotamine mesylate, or generic Dihydroergotamine mesylate injection **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 responded while on therapy Individual's condition has not worsened while on therapy
    a. Response is defined as:
        i. At least a 50% reduction in the number of migraine days per month from baseline
        ii. A reduction in the number of days of use of acute migraine-specific medications from baseline
        iii. No emergency visits for acute migraine treatment

3. Individual has been adherent with the medication

4. Uses at least one migraine prevention/prophylactic agent

5. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
    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

6. There are no significant interacting drugs

Renewal duration: 12 months

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MIGRANAL® (dihydroergotamine mesylate) nasal spray 4 mg/mL
TRUDHESA™ (dihydroergotamine mesylate) nasal spray 4 mg/mL

- 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 a Non-cancer Medications**

  2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Section B. Acute cluster headache episodes:
D.H.E. 45 (dihydroergotamine mesylate) injection
Dihydroergotamine mesylate injection

Criteria:

- **Criteria for initial therapy:** D.H.E. 45 (dihydroergotamine mesylate) injection or 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. A confirmed diagnosis of acute cluster headache episodes according to International Headache Society (IHS) International Classification of Headache Disorders (ICHD)

  4. Individual uses **either** oxygen or sumatriptan (subcutaneous or intranasal) or intranasal zolmitriptan or other abortive therapy for acute episodes of cluster headache

  5. The patient has had a previous trial of any **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 5HT1 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

7. There are no significant interacting drugs

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** D.H.E. 45 (dihydroergotamine mesylate) injection or generic dihydroergotamine mesylate injection is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

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 responded while on therapy
    a. Response is defined as **TWO** of the following:
        i. A reduction in the weekly cluster headache attack frequency from baseline

ii. At least a 50% reduction in the weekly cluster headache frequency from baseline
iii. No emergency room or urgent care visits for acute treatment

3. Individual has been adherent with the medication

4. Uses at least one prevention/prophylactic agent

5. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
   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

6. There are no significant interacting drugs

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 a Non-Cancer Medications**

  2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Description:

Migranal (dihydroergotamine mesylate) nasal spray, Trudhesa (dihydroergotamine mesylate) nasal spray, generic dihydroergotamine mesylate nasal spray, or D.H.E 45 (dihydroergotamine mesylate) injection 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.
D.H.E. 45 (dihydroergotamine mesylate) injection or generic dihydroergotamine mesylate injection is also indicated for the acute treatment of cluster headache episodes.

Dihydroergotamine binds with high affinity to 5-HT1Dα and 5-HT1Dβ receptors. It also binds with high affinity to serotonin 5-HT1A, 5-HT2A, and 5-HT2C receptors, noradrenaline α2A, α2B and α1 receptors, and dopamine D2L and D3 receptors. The therapeutic activity of dihydroergotamine in migraine is generally attributed to the agonist effect at 5-HT1D receptors. Two current theories have been proposed to explain the efficacy of 5-HT1D receptor agonists in migraine. One theory suggests that activation of 5-HT1D 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-HT1D 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:

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)
- 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:

Cluster headache: Diagnostic criteria for cluster headache require the following:
A. At least **five attacks** fulfilling criteria B through D
B. Severe or very severe **unilateral** 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. **Either or both** of the following:
1. At least **one** 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

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E. Not better accounted for by another ICHD-3 diagnosis
Episodic cluster headache: 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
Chronic cluster headache: 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
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[1]	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

1 Pain intensity
- Mild—Patient is aware of a headache but is able to continue daily routine with minimum alterations.
- Moderate—The headache inhibits daily activities; migraine pain is more noticeable but is not incapacitating.
- Severe—The headache is incapacitating such that patient is no longer able to engage in normal activities.

Resources:

Dihydroergotamine mesylate nasal spray product information, revised by Exelan Pharmaceuticals, Inc 06-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed July 23, 2021.

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Dihydroergotamine mesylate injection product information, revised by Apollo Pharmaceuticals, Inc 12-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed July 23, 2021.

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 July 23, 2021.

Migranal (dihydroergotamine mesylate) nasal spray product information, revised by Bausch Health US, LLC. 07-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed July 23, 2021.

Trudhesa (dihydroergotamine mesylate) nasal spray product information, revised by Impel NeuroPharma, Inc. 09-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed October 05, 2021.

Smith JH. Acute treatment of migraine in adults. In: UpToDate, Swanson JW, Goddeau RP (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed April 17, 2021.

Smith JH. Preventive treatment of episodic migraine in adults. In: UpToDate, Swanson JW, Goddeau RP (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed April 17, 2021.

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Garza I, Schwedt TJ. Medication overuse headache: Etiology, clinical features, and diagnosis. In: UpToDate, Swanson JW, Goddeau RP (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed April 17, 2021.

Garza I, Schwedt TJ. Medication overuse headache: Treatment and prognosis. In: UpToDate, Swanson JW, Goddeau RP (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed April 17, 2021.

May A. Cluster headache: Treatment and prognosis. In: UpToDate, Swanson JW, Goddeau RP (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed April 17, 2021.

Consensus Statement: The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. Headache 2019; 59:1-18. Accessed on August 5, 2020. Re-reviewed April 20, 2021.