UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2125-10
Program	Prior Authorization/Medical Necessity
Medication	Dihyroergotamine nasal spray (Migranal®)*, Ergomar® (ergotamine), Trudhesa®* (dihydroergotamine nasal spray)
P&T Approval Date	4/2017, 6/2017, 3/2018, 3/2019, 1/2020, 1/2021, 11/2021, 11/2022, 11/2023, 11/2024
Effective Date	2/1/2025

1. Background:

Migranal* (dihydroergotamine) and Trudhesa* (dihydroergotamine) are indicated for the acute treatment of migraine headaches with or without aura. Neither Migranal* nor Trudhesa* are intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.

Ergomar is indicated to abort or prevent vascular headache, for example, migraine, migraine variants or a so-called "histaminic cephalalgia". Ergomar should not be used for chronic daily administration.

The American Headache Society consensus statement recommends use of nonsteroidal anti-inflammatory drugs (NSAIDs), nonopioid analgesics, acetaminophen, or caffeinated analgesic combinations (e.g., aspirin + acetaminophen + caffeine) for mild-to-moderate attacks and migraine-specific agents (triptans, dihydroergotamine [DHE], small-molecule CGRP receptor antagonists, selective serotonin (5- HT1F) receptor agonist for moderate or severe attacks and mild-to- moderate attacks that respond poorly to nonspecific therapy.
This program requires a member to try one oral triptan and two nasal triptans prior to receiving coverage for nasal dihydroergotamine or two oral triptans prior to receiving coverage of Ergomar.

2. Coverage Criteria[a]:

A. Dihydroergotamine Nasal Spray (Migranal*) or Trudhesa* will be approved based on **all** of the following criteria:

1. Diagnosis of moderate to severe migraine headaches with or without aura.

-AND-

2. History of failure (after at least 3 migraine episodes and a minimum of a 30-day trial), contraindication, or intolerance to **one** of the following oral triptans (Document duration of trial):

   a. almotriptan (Axert®)
   b. eletriptan (Relpax®)

c. frovatriptan (Frova®)
d. naratriptan (Amerge®)
e. rizatriptan (Maxalt®/Maxalt-MLT®)
f. sumatriptan (Imitrex®)
g. zolmitriptan (Zomig®)

-AND-

3. History of failure (after at least 3 migraine episodes and a minimum of a 30-day trial), contraindication, or intolerance to **both** of the following:

   a. sumatriptan nasal spray (generic Imitrex nasal spray)
   b. Zomig nasal spray (zolmitriptan)

B. Ergomar (ergotamine) will be approved based on **all** of the following criteria:

1. Diagnosis of moderate to severe migraine headaches with or without aura.

-AND-

2. History of failure (after at least 3 migraine episodes and a minimum of a 30-day trial), contraindication, or intolerance to **two** of the following oral triptans (Document duration of trial):

   a. almotriptan (Axert)
   b. eletriptan (Relpax)
   c. frovatriptan (Frova)
   d. naratriptan (Amerge)
   e. rizatriptan (Maxalt/Maxalt MLT)
   f. sumatriptan (Imitrex)
   g. zolmitriptan (Zomig)

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

***** Brand Migranal and Trudhesa are typically excluded from coverage.

3. Additional Clinical Programs:

- Supply limits may apply.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Migranal [package insert]. Bridgewater, NJ: Bausch Health US, LLC.; September 2022.
2. Ergomar [package insert]. Deerfield, IL; TerSera Therapeutics; February 2020.
3. Trudhesa [package insert]. Seattle, WA: Impel NeuroPharma Inc; August 2023.
3. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache.* 2021: 61 1021-39.

Program	Prior Authorization/Medical Necessity – Dihydroergotamine nasal spray
Change Control	
Date	Change
4/2017	New program.
6/2017	Added Ergomar to criteria. State mandate reference language updated.
3/2018	Added documentation of drug name and date of trials into the criteria.
3/2019	Annual review. Modified documentation language, added statement regarding use of automated process and updated references.
1/2020	Removed Zomig which became non-preferred. Updated references.
1/2021	Annual review, updated references.
11/2021	Added Trudhesa. Updated the trial language to include 3 migraine episodes or a minimum of 30 days. Added Zomig nasal spray to requirement for dihydroergotamine nasal spray products.
11/2022	Annual review. Added Trudhesa typically excluded from coverage. Updated references.
11/2023	Annual review. Updated background section and references.
11/2024	Annual review. Updated references.