

Program Number	2025 P 3196-1
Program	Step Therapy
Medication	Brekiya® (dihydroergotamine)*, Dihydroergotamine nasal spray (Migranal®)*, Ergomar® (ergotamine), Trudhesa®* (dihydroergotamine nasal spray)
P&T Approval Date	11/2025
Effective Date	2/1/2026

1. Background:

Brekiya* (dihydroergotamine) nasal spray is indicated for the acute treatment of migraine with or without aura and the acute treatment of cluster headaches in adults. Migranal* (dihydroergotamine) and Trudhesa* (dihydroergotamine) are indicated for the acute treatment of migraine headaches with or without aura. Brekiya*, Migranal* and Trudhesa* are not 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 cephalgia". 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.

2. Coverage Criteria^a:

A. Brekiya* will be approved based on both of the following criteria:

1. History of failure (after at least 3 migraine episodes and a minimum of a 30-day trial), contraindication, or intolerance to dihydroergotamine (generic D.H.E.) injection
-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 triptans (oral or nasal) (Document drug and 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.

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

1. 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-

2. 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)

Authorization will be issued for 12 months.

C. Ergomar (ergotamine) will be approved based on the following criterion:

1. 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 drug and 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.

* Brekiya, 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. Brekiya [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2025.
2. Migranal [package insert]. Bridgewater, NJ: Bausch Health US, LLC.; September 2022.
3. Ergomar [package insert]. Deerfield, IL; TerSera Therapeutics; February 2020.
4. Trudhesa [package insert]. Seattle, WA: Impel NeuroPharma Inc; August 2023.
5. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021; 61: 1021-39.

Program	Step Therapy – Ergotamine products - Brekiya, Dihydroergotamine nasal spray, Ergomar, Trudhesa
Change Control	
Date	Change
11/2025	New program.