



## STEP THERAPY POLICY

**POLICY:** Migraine Medication Step Therapy Policy

### **Injectable Medications**

- Brekiya<sup>®</sup> (dihydroergotamine mesylate subcutaneous injection – Amneal)
- Imitrex<sup>®</sup> (sumatriptan injection – GlaxoSmithKline, generic)
- Zembrace<sup>®</sup> SymTouch<sup>®</sup> (sumatriptan injection – Dr. Reddy’s Labs)

### **Oral Triptans**

- Almotriptan tablets (generic to discontinued Axert<sup>®</sup>)
- Frova<sup>®</sup> (frovatriptan tablets – Endo, generic)
- Imitrex<sup>®</sup> (sumatriptan tablets – GlaxoSmithKline, generic)
- Maxalt<sup>®</sup> (rizatriptan tablets – Merck, generic)
- Maxalt MLT<sup>®</sup> (rizatriptan orally disintegrating tablets – Merck, generic)
- Naratriptan tablets (generic to discontinued Amerge<sup>®</sup>)
- Relpax<sup>®</sup> (eletriptan tablets – Pfizer, generic)
- Symbravo<sup>®</sup> (meloxicam and rizatriptan tablets – Axsome)
- Treximet<sup>®</sup> (sumatriptan and naproxen sodium tablets – Pernix, generic)
- Zomig<sup>®</sup> (zolmitriptan tablets – AstraZeneca [brand discontinued 1/2023], generic)
- zolmitriptan orally disintegrating tablets (generic to discontinued Zomig-ZMT<sup>®</sup>)

### **Nasal Medications**

- Imitrex<sup>®</sup> (sumatriptan nasal spray – GlaxoSmithKline, generic)
- Migranal<sup>®</sup> (dihydroergotamine mesylate nasal spray – Valeant, generic)
- Onzetra<sup>®</sup> Xsail<sup>®</sup> (sumatriptan nasal powder – Currax)
- Tosymra<sup>®</sup> (sumatriptan nasal spray – Promius)
- Trudhesa<sup>™</sup> (dihydroergotamine mesylate nasal spray – Impel)
- Zomig<sup>®</sup> (zolmitriptan nasal spray – AstraZeneca, generic)

**REVIEW DATE:** 11/12/2025

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### **INSTRUCTIONS FOR USE**

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER’S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER’S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER’S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY

DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

## CIGNA NATIONAL FORMULARY COVERAGE:

### OVERVIEW

All of the triptan medications, including Treximet (the combination sumatriptan-naproxen sodium agent) and Symbravo (the combination rizatriptan-meloxicam agent), are indicated for the **treatment of migraine headache** with or without aura in adults and are not intended to be used as prophylactic migraine therapy or to manage hemiplegic or basilar migraine.<sup>1-15</sup> Only sumatriptan injection is approved for the treatment of cluster headache.<sup>10</sup> Safety and efficacy have not been established for treatment of cluster headache for the oral dosage forms of all triptans.<sup>1-8</sup> Some of the triptan medications are also indicated for use in children and/or adolescents. Almotriptan is approved for the treatment of migraine headache pain in adolescent patients 12 to 17 years of age with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated).<sup>6</sup> Rizatriptan is approved for the acute treatment of migraine with or without aura in patients  $\geq 6$  years of age.<sup>3</sup> Treximet and zolmitriptan nasal spray are approved for the acute treatment of migraine with or without aura in patients  $\geq 12$  years of age.<sup>8,11</sup>

Rizatriptan orally disintegrating tablets and zolmitriptan orally disintegrating tablets offer the convenience of not requiring liquids for oral administration.<sup>4,5</sup> Treximet and Symbravo offer the convenience of two agents (triptan and non-steroidal anti-inflammatory drug [NSAID]) with pharmacologically different mechanisms of action in one tablet.<sup>9,15</sup>

Migranal and Trudhesa, ergot alkaloids, are nasal sprays indicated for the **acute treatment of migraine headaches** in adults with or without aura.<sup>16,17</sup> Migranal and Trudhesa are not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine. Brekiya, also an ergot alkaloid, is a subcutaneous injection indicated for the **acute treatment of migraine** with or without aura and the **acute treatment of cluster headaches** in adults.<sup>18</sup> Brekiya is not indicated for the preventive treatment of migraine or for the management of hemiplegic migraine or migraine with brainstem aura.

## **POLICY STATEMENT**

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

**Step 1:** generic eletriptan tablets, generic naratriptan tablets, generic rizatriptan tablets, generic rizatriptan orally disintegrating tablets, generic sumatriptan tablets, generic sumatriptan nasal spray, generic sumatriptan injection, generic zolmitriptan orally disintegrating tablets, generic zolmitriptan tablets

**Step 2:** generic almotriptan tablets, Brekiya, Frova tablets (brand and generic), Imitrex tablets, Imitrex Nasal Spray, Imitrex Injection, Maxalt tablets, Maxalt MLT, Migranal (brand and generic), Onzetra Xsail, Relpax, Symbravo, Tosymra, Treximet tablets (brand and generic), Trudhesa, Zembrace Symtouch, Zomig tablets, Zomig nasal spray (brand and generic)

***Migraine Medication Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.***

## **CRITERIA**

**1.** If the patient has tried one Step 1 Product, approve a Step 2 Product.

## **REFERENCES**

1. Frova<sup>®</sup> tablets [prescribing information]. Malvern, PA; Endo; August 2018.
2. Naratriptan tablets [prescribing information]. Berkeley Heights, NJ: Hikma; March 2023.
3. Maxalt<sup>®</sup> tablets and Maxalt-MLT<sup>®</sup> orally disintegrating tablets [prescribing information]. Whitehouse Station, NJ: Merck; October 2019.
4. Zomig<sup>®</sup> tablets [prescribing information]. Wilmington, DE: AstraZeneca; December 2018.
5. Imitrex<sup>®</sup> tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; February 2024.
6. Almotriptan tablets [prescribing information]. Morgantown, WV: Mylan; May 2017.
7. Relpax<sup>®</sup> tablets [prescribing information]. New York, NY: Pfizer; March 2020.
8. Treximet<sup>®</sup> tablets [prescribing information]. Brentwood, TN: Currax; November 2024.
9. Imitrex<sup>®</sup> nasal spray [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
10. Imitrex<sup>®</sup> injection [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2021.
11. Zomig<sup>®</sup> nasal spray [prescribing information]. Wilmington, DE: AstraZeneca; December 2018.
12. Onzetra<sup>®</sup> Xsail<sup>®</sup> nasal powder [prescribing information]. Morristown, NJ: Currax; December 2019.
13. Zembrace<sup>®</sup> SymTouch<sup>®</sup> injection [prescribing information]. Princeton, NJ: Promius; June 2019.
14. Tosymra<sup>®</sup> nasal spray [prescribing information]. Princeton, NJ: Promius; January 2019.
15. Symbravo<sup>®</sup> tablets [prescribing information]. New York, NY: Axsome; January 2025.

16. Migranal® nasal spray [prescribing information]. Bridgewater, NJ: Valeant; April 2022.
17. Trudhesa™ nasal spray [prescribing information]. Seattle, WA: Impel; September 2021.
18. Brekiya® injection [prescribing information]. Bridgewater, NJ: Amneal; May 2025.

## HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	<b>Alsuma:</b> Removed from policy. Obsolete for > 3 years. <b>Sumavel DosePro:</b> Removed from policy. Obsolete for > 3 years.	03/22/2023
Annual Revision	<b>Axert:</b> Brand name product removed from policy. Obsolete for > 3 years.	04/03/2024
Early Annual Revision	<b>Generic almotriptan tablets:</b> Removed from Step 1 Products and added to Step 2 Products. <b>Generic frovatriptan tablets:</b> Removed from Step 1 Products and added to Step 2 Products. <b>Zomig-ZMT (brand product):</b> Removed from Step 2 Products; obsolete for ≥ 3 years.	01/29/2025
Selected Revision	<b>Removal of Note:</b> "Note: Zomig Nasal Spray with DAW 9 (indicating that substitution is allowed by the prescriber but the Plan requests brand) will also count as a Step 1 Product" was removed from criteria because Zomig 5mg nasal spray has been permanently removed from the Standard DAW9 Program.	03/12/2025
Selected Revision	<b>Symbravo:</b> Added to the policy as a Step 2 Product.	07/09/2025
Annual Revision	<b>Brekiya:</b> Added to the policy as a Step 2 Product. <b>Amerge (brand product):</b> Removed from Step 2 products; obsolete for ≥ 3 years.	11/12/2025

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