BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
1310 G Street, N.W.
Washington, D.C. 20005
202.942.1000
Fax 202.942.1125

5.70.023

Section:	Prescription Drugs	**Effective Date:**	October 1, 2023
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	December 6, 2012
Subject:	Migraine Powders	**Page:**	1 of 6

Last Review Date: September 8, 2023

Migraine Powders

Description

Sumatriptan powder, Zolmitriptan powder

Background
The selective serotonin receptor agonists, or “triptans", are a class of medications that have the ability to stop a migraine. Triptans work by binding to serotonin receptors in the brain. Specifically, per Drug Facts and Comparisons pharmacology of the Serotonin 5-HT_1 Receptor Agonists (Triptans): The vascular 5-HT_1 receptor subtype is present on the human basilar artery and in the vasculature of isolated human dura mater. Current theories on the etiology of migraine headaches suggest that symptoms are caused by local cranial vasodilation or the release of vasoactive and proinflammatory peptides from sensory nerve endings in an activated trigeminal system. The therapeutic activity of the serotonin 5-HT_1 receptor agonists in migraine most likely can be attributed to agonist effects at 5-$HT_{1B/1D}$ receptors on the extracerebral, intracranial blood vessels that become dilated during a migraine attack and on nerve terminals in the trigeminal system. Activation of these receptors results in cranial vessel constriction, inhibition of neuropeptide release, and reduced transmission in trigeminal pain pathways (1).

Regulatory Status
FDA-approved indication: Migraine powders are indicated for the acute treatment of migraine attacks with or without aura in adults. Migraine powders are not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of migraine powders has not been established for cluster headache in any dosage form other than injectable (2-3).

This class of medications has potentially serious side effects, especially when taken in high doses. Life-threatening disturbances of cardiac rhythm and myocardial infarction have been reported, as well as stroke. Excessive use of triptans can lead to medication overuse headache (2-3).

Off-Label Use:
Compounded topical preparations of migraine powders have not been proven to be safe or effective.

Triptans have been found to be safe and effective in the pediatric and adolescent population (4).

Related policies
5-HT1 Agonists, Butalbital analgesics, Dihydroergotamine Nasal Sprays, Elyxyb, Maxalt, Migraine CGRP Antagonists IV, Migraine CGRP Antagonists Nasal, Migraine CGRP Antagonists Oral, Migraine CGRP Antagonists SC

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Migraine powders may be compounded into dosage forms that may be considered **medically necessary** if the conditions indicated below are met.

Migraine powders may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 6 years of age or older
Ages 6-11 years must be prescribed by a neurologist

Diagnoses

Patient must have **ONE** of the following:

1. Migraine, with aura (classic or classical)
2. Migraine, without aura (common)
3. Cluster headache – acute treatment (Injectable **ONLY**)

AND ALL of the following:

a. Patient is currently using migraine prophylactic therapy **OR** the patient has had an inadequate treatment response, intolerance, or contraindication to migraine prophylactic therapy (e.g., divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, etc.)
b. **NO** hemiplegic migraine
c. **NO** basilar migraine
d. **NO** dual therapy with a calcitonin gene related peptide (CGRP) antagonist for acute migraine treatment (e.g., Nurtec ODT, Ubrelvy)
e. **NO** dual therapy with Reyvow (lasmiditan) or Elyxyb (celecoxib)
f. **NO** other PA on file for any triptan agent
g. The requested dose is **not** commercially available
h. The strength does **not** exceed FDA approved limit for requested dosage form
i. The dosage form must be commercially available

Prior – Approval *Renewal* Requirements

Age

6 years of age or older
Ages 6-11 must be prescribed by a neurologist

Diagnoses

Patient must have **ONE** of the following:

1. Migraine, with aura (classic)
2. Migraine, without aura (common)
3. Cluster headache – acute treatment (Injectable **ONLY**)

AND ALL of the following:

a. **NO** hemiplegic migraine
b. **NO** basilar migraine
c. **NO** dual therapy with a calcitonin gene related peptide (CGRP) antagonist for acute migraine treatment (e.g., Nurtec ODT, Ubrelvy)
d. **NO** dual therapy with Reyvow (lasmiditan) or Elyxyb (celecoxib)
e. **NO** other PA on file for any triptan agent
f. The requested dose is **not** commercially available
g. The strength does **not** exceed FDA approved limit for requested dosage

form

h. The dosage form must be commercially available

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Migraine powders are indicated for the acute treatment of migraine attacks with or without aura in adults. Migraine powders are not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of migraine powders has not been established for cluster headache in any dosage form other than injectable. Migraine powders must be prescribed by a neurologist for ages 6-11 (1-4).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Triptan powders while maintaining optimal therapeutic outcomes.

References

1. Serotonin 5-HT1 Receptor Agonists (Triptans). Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; December 2017.
2. Zomig and Zomig-ZMT [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2019.
3. Imitrex tablets [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2020.
4. Evers S., The Efficacy of Triptans in Childhood and Adolescence. *Migraine Curr Pain Headache Rep*. 2013;17(7):342.

Policy History

Date	Action
September 2012	New Addition
December 2012	Changed quantity limit to 1.5 x FDA-approved dosage. Annual review and update
June 2014	Addition of zolmitriptan powder, addition of specific wording to exclude topical preparations and revision of age to allow pediatric and adolescent use. Annual review and update.
September 2014	Annual editorial review and reference update
June 2015	Annual review
March 2016	Annual editorial review and reference update Policy number changed from 5.02.23 to 5.70.23
March 2017	Annual editorial review
March 2018	Annual editorial review and reference update
November 2018	Annual editorial review and reference update. Addition of no dual therapy with CGRP antagonist requirement and no dual therapy with another PA for any triptan agent
March 2019	Annual review
November 2019	Addition of no dual therapy with Reyvow
December 2019	Annual review
March 2020	Annual review and reference update
June 2020	Annual review
April 2021	Added no dual therapy with a CGRP antagonist for acute migraine treatment. Revised no dual therapy requirement after 6 months of a prophylactic CGRP antagonist. Added initiation requirement to be on a migraine prophylactic therapy or have an inadequate treatment response, intolerance, or contraindication to migraine prophylactic therapy. Changed cluster headache indication from “cluster headache-treatment of acute episode” to “cluster headache- acute treatment”.
June 2021	Annual review and reference update
September 2021	Annual review and reference update
March 2022	Annual review and reference update. Per SME, removed requirement of “no dual therapy after 6 months with a prophylactic CGRP antagonist”
April 2022	Added no dual therapy with Elyxyb
June 2022	Annual review
June 2023	Annual review. Changed policy number to 5.70.023
September 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.