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-HT1 Receptor Agonists (Triptans): The vascular 5-HT1 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-HT1 receptor agonists in migraine most likely can be attributed to agonist effects at 5-HT1B/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**
Amerge, Axert, Butalbital analgesics, Frova, Maxalt, Migraine Calcitonin Gene Related Peptide (CGRP) Antagonists, Migranal Nasal Spray, Relpax, Reyvow, Sumatriptan, Sumatriptan Injection, Zomig

**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** in patients 6 years of age or older. Migraine powders must be prescribed by a neurologist for ages 6 – 11. The requested compound may not be commercially available and should not exceed the commercially available strength for the requested dosage form.

Migraine powders are considered **investigational** in patients below 6 years of age, for the diagnoses of hemiplegic or basilar migraine and at doses that exceed the FDA limits or compounded into a topical dosage form.

**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 – treatment of acute episode (Injectable **ONLY**)

**AND NONE** of the following:
1. Hemiplegic migraine
2. Basilar migraine
3. Dual therapy after 6 months of calcitonin gene related peptide (CGRP) antagonist therapy
4. Dual therapy with Reyvow (lasmiditan)
5. Another PA on file for any triptan agent

**AND ALL** of the following:
1. The requested dose is **not** commercially available
2. The strength does **not** exceed FDA approved limit for requested dosage form
3. The dosage form must be commercially available

**Prior – Approval Renewal Requirements**
Same as above

**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

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>September 2012</td>
<td>New Addition</td>
</tr>
<tr>
<td>December 2012</td>
<td>Changed quantity limit to 1.5 x FDA-approved dosage. Annual review and update.</td>
</tr>
<tr>
<td>June 2014</td>
<td>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.</td>
</tr>
<tr>
<td>September 2014</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>June 2015</td>
<td>Annual review</td>
</tr>
<tr>
<td>March 2016</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>March 2017</td>
<td>Policy number changed from 5.02.23 to 5.70.23</td>
</tr>
<tr>
<td>March 2018</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>November 2018</td>
<td>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</td>
</tr>
<tr>
<td>March 2019</td>
<td>Annual review</td>
</tr>
<tr>
<td>November 2019</td>
<td>Addition of no dual therapy with Reyvow</td>
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Keywords
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<td>Original Policy Date:</td>
<td>December 6, 2012</td>
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<td>Subject</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.