Zomig

Description

Zomig / Zomig-ZMT (zolmitriptan)

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 indications:
Zomig is supplied as a nasal spray (5mg), tablets (2.5mg and 5mg) and orally disintegrating tablets (2.5mg and 5mg) (2-3).

All forms of the product are indicated for the acute treatment of migraine with or without aura in adults (2-3).
Limitations of use: (2-3)

- Use only after a clear diagnosis of migraine has been established
- Not intended for the prophylactic therapy of migraine
- Not indicated for the treatment of cluster migraine
- Not recommended in patients with moderate to severe hepatic impairment

Zomig is not intended for use in the management of hemiplegic or basilar migraine (2-3).

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

Safety and effectiveness of Zomig have not been established for cluster headache, which is present in an older, predominantly male population (2-3).

Related policies
Amerge, Axert, Butalbital analgesics, Frova, Maxalt, Migraine Calcitonin Gene Related Peptide (CGRP) Antagonists, Migraine Powders, Migranal Nasal Spray, Relpax, Reyvow, Sumatriptan, Sumatriptan Injection

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

Zomig may be considered medically necessary for the treatment of migraine (classic or common) and if the conditions indicated below are met.

Zomig may be considered investigational for patients below 6 years of age and for all other indications.

Prior-Approval 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)
AND NONE of the following:
   a. Hemiplegic migraine
   b. Basilar migraine
   c. Dual therapy after 6 months of calcitonin gene related peptide (CGRP) antagonist therapy
   d. Dual therapy with Reyvow (lasmiditan)
   e. Another PA on file for any triptan agent

Prior – Approval Renewal Requirements
Same as above

Policy Guidelines

Pre-PA Allowance
Age
   12 years of age or older
   No Pre-PA Allowance for 6-11 years of age

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>2.5 mg tablets</td>
<td>36 tablets per 90 days OR</td>
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<tr>
<td>2.5 mg nasal spray</td>
<td>36 units per 90 days OR</td>
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<td>5 mg tablets</td>
<td>18 tablets per 90 days OR</td>
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<td>5 mg nasal spray</td>
<td>18 units per 90 days</td>
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Prior - Approval Limits

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<th>Quantity</th>
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<tr>
<td>2.5 mg tablets</td>
<td>54 tablets per 90 days OR</td>
</tr>
<tr>
<td>2.5 mg nasal spray</td>
<td>54 units per 90 days OR</td>
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<tr>
<td>5 mg tablets</td>
<td>27 tablets per 90 days OR</td>
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<tr>
<td>5 mg nasal spray</td>
<td>24 units per 90 days</td>
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Duration 6 months

Prior – Approval Renewal Limits
Same as above
Rationale

Summary
Migraine is a chronic, recurrent condition that affects millions of people worldwide. Triptans are serotonin (5-HT) receptor agonists that interrupt attacks or episodes of migraine, but do not prevent migraines from happening. 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. Triptans have been found to be safe and effective in the pediatric and adolescent population (1-4).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Zomig while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>September 2011</td>
<td>New Policy</td>
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<tr>
<td>September 2012</td>
<td>Annual editorial review and reference update.</td>
<td></td>
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<tr>
<td>December 2012</td>
<td>Changed quantity limit to 1.5 x FDA-approved dosage.</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>April 2013</td>
<td>Revised quantity limits to allow mail order to fill correctly</td>
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<tr>
<td>June 2014</td>
<td>Revision of age to allow pediatric and adolescent use.</td>
<td>Annual editorial review and reference update.</td>
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<tr>
<td></td>
<td>Revision of dose to allow pediatric and adolescent use.</td>
<td>Addtion of 2.5mg nasal spray</td>
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<td>September 2014</td>
<td>Annual editorial review and reference update.</td>
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<tr>
<td>March 2016</td>
<td>Annual editorial review and reference update</td>
<td>Policy number changed from 5.02.22 to 5.70.22</td>
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Section: Prescription Drugs  Effective Date: January 1, 2020
Subsection: Analgesics and Anesthetics  Original Policy Date: September 8, 2011
Subject: Zomig  Page: 5 of 5

March 2017  Annual editorial review and reference update
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
September 209  Revised quantity limits to quantity per 90 days
November 2019  Addition of no dual therapy with Reyvow
December 2019  Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.