Frova (frovatriptan)

**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: Frova is a serotonin receptor agonist (triptan) indicated for the acute treatment of migraine attacks with or without aura in adults (2).

**Limitations of Use:** (2)
1. Use only after clear diagnosis of migraine has been established.
2. Not indicated for the prophylactic therapy of migraine.
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 (MOH) (2).

Frova is contraindicated in patients who have a history of coronary artery disease or coronary artery vasospasm. It is also contraindicated in Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders, history of stroke, transient ischemic attack, hemiplegic or basilar migraine, peripheral vascular disease or ischemic bowel disease (2).

**Off Label Use:**
Triptans have been found to be safe and effective in the pediatric and adolescent population (3).

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

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**Policy**

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

Frova may be considered **medically necessary** in patients 6 years of age or older for the treatment of migraine (classic or common) and if the conditions indicated below are met.

Frova may be considered **investigational** patients less than 6 years of age and for all other indications.

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**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

Quantity

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<th>Strength</th>
<th>Quantity</th>
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<td>36 tablets per 90 days</td>
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Prior - Approval Limits

Quantity

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<td>2.5 mg</td>
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Duration 6 months

Prior – Approval Renewal Limits
Same as above

Rationale
Summary
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 (3).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Frova 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 2011</td>
<td>New Policy</td>
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<tr>
<td>December 2012</td>
<td>Changed quantity limit to 1.5 x FDA-approved dosage. Annual review and update</td>
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<tr>
<td>September 2014</td>
<td>Revision of age to allow pediatric and adolescent use. Annual editorial review and reference update</td>
</tr>
<tr>
<td>March 2016</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>March 2017</td>
<td>Annual editorial review and reference update</td>
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<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>September 2019</td>
<td>Revised quantity limits to quantity per 90 days</td>
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<tr>
<td>November 2019</td>
<td>Addition of no dual therapy with Reyvow</td>
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<td>December 2019</td>
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Keywords
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<th>Prescription Drugs</th>
<th><strong>Effective Date:</strong></th>
<th>January 1, 2020</th>
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<tr>
<td><strong>Subsection:</strong></td>
<td>Analgesics and Anesthetics</td>
<td><strong>Original Policy Date:</strong></td>
<td>September 8, 2011</td>
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<td><strong>Subject:</strong></td>
<td>Frova</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.