Relpax (eletriptan hydrobromide)

**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-HT₁A 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).

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 (1).

**Regulatory Status**
FDA-approved indication: Relpax is indicated for the acute treatment of migraine with or without
aura in adults (2).

Limitations of use: (2)
- Use only after a clear diagnosis of migraine has been established
- Not indicated for the prophylactic therapy of migraine
- Not indicated for the treatment of cluster headache

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, Frova, Maxalt, Migraine Calcitonin Gene Related Peptide (CGRP) Antagonists, Migraine Powders, Migranal Nasal Spray, 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.

Relpx may be considered medically necessary for the treatment of migraine with or without aura (classic or common) and if the conditions indicated below are met.

Relpx 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*

**Quantity**

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**Prior - Approval Limits**

**Quantity**

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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 (1-3).

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

References
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<th>Prescription Drugs</th>
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<td>Analgesics and Anesthetics</td>
<td><strong>Original Policy Date:</strong></td>
<td>September 8, 2011</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.