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Section:	Prescription Drugs	**Effective Date:**	April 1, 2022
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	September 8, 2011
Subject:	Relpax	**Page:**	1 of 5

Last Review Date: March 11, 2022

Relpax

Description

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-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).

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, Dihydroergotamine Nasal Sprays, Frova, Maxalt, Migraine CGRP Antagonists IV, Migraine CGRP Antagonists SC, Migraine CGRP Antagonists Oral, Migraine Powders, 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.

Relpax 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.

Relpax 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 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)
f. **NO** other PA on file for any triptan agent

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)

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)
e. **NO** other PA on file for any triptan agent

Policy Guidelines

Pre - PA Allowance

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

Quantity

Strength	Quantity

20 mg	36 tablets per 90 days **OR**
40 mg	18 tablets per 90 days

Prior - Approval Limits

Quantity

Strength	Quantity
20 mg	54 tablets per 90 days **OR**
40 mg	24 tablets per 90 days

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

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. Relpax [Package Insert]. New York, NY: Pfizer Inc.; March 2020.
3. Evers S. The Efficacy of Triptans in Childhood and Adolescence Migraine. Curr Pain Headache Rep. 2013 July;17(7)342.

Policy History

Date	Action
September 2011	New Policy
September 2012	Annual editorial review and reference update.
December 2012	Changed quantity limit to 1.5 x FDA-approved dosage Annual review and update
April 2013	Revised quantity limits to allow mail order to fill correctly
September 2014	Revision of age to allow pediatric and adolescent use. Annual editorial review and reference update
March 2016	Annual editorial review and reference update Policy number changed from 5.02.19 to 5.70.19
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
September 2019	Revised quantity limits to quantity per 90 days
November 2019	Addition of no dual therapy with Reyvow
December 2019	Annual review
March 2020	Annual review
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
June 2021	Annual review and reference update
September 2021	Annual review
March 2022	Annual review. Per SME, removed requirement of “no dual therapy after 6 months with a prophylactic CGRP antagonist”

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 11, 2022 and is effective on April 1, 2022.