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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	June 9, 2009
Subject:	Axert	**Page:**	1 of 5

Last Review Date: March 12, 2021

Axert

Description

Axert (almotriptan)

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-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).

Regulatory Status
FDA-approved indication: Axert is a 5HT1B/1D receptor agonist (triptan) indicated for the treatment of acute treatment of migraine attacks in adults with a history of migraine with or without aura. Axert is also indicated for the acute treatment of migraine headache pain in adolescents age 12 to 17 years with a history of migraine with or without aura, and who have migraine attacks usually lasting 4 hours or more. (2)

Limitations of use: (2)
- Use only after a clear diagnosis of migraine has been established.

- In adolescents age 12 to 17 years, efficacy of Axert on migraine-associated symptoms was not established.
- Not intended for the prophylactic therapy of migraine.
- Not indicated for the treatment of cluster headache.

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 Contraindications include: ischemic heart disease, coronary artery vasospasm, or other significant underlying cardiovascular disease, cerebrovascular syndromes (e.g., history of stroke or TIA), peripheral vascular disease (including ischemic bowel disease), uncontrolled hypertension, use of Axert within 24 hours of an ergotamine-containing, or ergot-type medication, or of another 5-HT 1 agonist, e.g., another triptan, hemiplegic or basilar migraine , and known hypersensitivity to Axert. (2)

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

Related policies
Amerge, Butalbital analgesics, Frova, Maxalt, Migraine CGRP Antagonists IV, Migraine CGRP Antagonists SC, Migraine CGRP Antagonists Oral, Migraine Powders, 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.

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

Axert 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

Strength	Quantity
6.25 mg	48 tablets per 90 days **OR**
12.5 mg	24 tablets per 90 days

Prior - Approval Limits

Quantity

Strength	Quantity
6.25 mg	72 tablets per 90 days **OR**

12.5 mg	36 tablets per 90 days

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Axert is indicated for the treatment of acute treatment of migraine attacks in adults with a history of migraine with or without aura. Axert is not intended for the prophylactic therapy of migraine or in the treatment of cluster headache. 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 (2). 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 Axert 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; October 2019. Accessed January 9, 2019.
2. Axert [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; May 2017.
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
June 2009	The FDA has approved Axert (almotriptan malate tablets, from Ortho-McNeil Janssen), a selective 5-HT1B/1D receptor agonist, for the acute treatment of migraine headache in adolescents 12-17 years of age with a history of migraine attacks lasting ≥4 hours (1)
April 2011	Annual editorial and reference update

December 2012	Changed quantity limit to 1.5 x FDA-approved dosage Annual review and update
September 2014	Revision of age to allow pediatric and adolescent use. Annual editorial review and reference update
July 2015	Annual editorial review and reference update
March 2016	Annual editorial review and reference update Policy number changed from 5.02.05 to 5.70.05
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 and reference update
June 2020	Annual review
March 2021	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.