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-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: 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-HT1 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 Calcitonin Gene Related Peptide (CGRP) Antagonists, 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**

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>6.25 mg</td>
<td>48 tablets per 90 days OR</td>
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<tr>
<td>12.5 mg</td>
<td>24 tablets per 90 days</td>
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**Prior - Approval Limits**

**Quantity**

<table>
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<th>Strength</th>
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<tr>
<td>6.25 mg</td>
<td>72 tablets per 90 days OR</td>
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5.70.05

**Section:** Prescription Drugs  
**Effective Date:** January 1, 2020  
**Subsection:** Analgesics and Anesthetics  
**Original Policy Date:** June 9, 2009  
**Subject:** Axert  
**Page:** 4 of 5

<table>
<thead>
<tr>
<th>12.5 mg</th>
<th>36 tablets per 90 days</th>
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</table>

**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**

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>June 2009</td>
<td>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)</td>
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<tr>
<td>April 2011</td>
<td>Annual editorial and reference update</td>
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<tr>
<td>Date</td>
<td>Update</td>
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<td>-------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
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<tr>
<td>December 2012</td>
<td>Changed quantity limit to 1.5 x FDA-approved dosage</td>
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<tr>
<td>September 2014</td>
<td>Revision of age to allow pediatric and adolescent use.</td>
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<tr>
<td>July 2015</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>
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<tr>
<td>March 2017</td>
<td>Policy number changed from 5.02.05 to 5.70.05</td>
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<tr>
<td>March 2018</td>
<td>Annual editorial review and reference update</td>
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<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>
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<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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<tr>
<td>December 2019</td>
<td>Annual review</td>
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**Keywords**

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