ALMOTRIPTAN (AXERT®)
UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS: 5-HT1 agonists

BRAND NAME: Axert (almotriptan) 6.25 and 12.5 mg oral tablet

FDA INDICATIONS:
- Oral almotriptan is indicated for the acute treatment of migraine with or without aura in adults. The 5-HT1 agonists are not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness has also not been established for cluster headache.

For members on the Basic Open Formulary, before approval of a nonpreferred agent is given, up to two preferred agents must be tried. Please consult the formulary list as these agents may change over time.

QUANTITY LIMITATIONS

EXTENDED SUPPLY
300 mg per 90 days

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Axert 6.25 mg</td>
<td>48 tablets</td>
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<tr>
<td>Axert 12.5 mg</td>
<td>24 tablets</td>
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</tbody>
</table>

If the patient is requiring amounts in excess of these numbers, please follow the quantity limitations criteria developed for Axert.

RESTRICTED ACCESS COVERAGE AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>Restricted Access Triptans</th>
<th>Non-Restricted Access Triptans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alsuma (sumatriptan) auto-injector</td>
<td>Amerge (naratriptan) tablets</td>
</tr>
<tr>
<td>Axert (almotriptan) tablets</td>
<td>Imitrex (sumatriptan) tablets</td>
</tr>
<tr>
<td>Frova (frovatriptan) tablets</td>
<td>Imitrex (sumatriptan) nasal solution</td>
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<tr>
<td>Relpax (eletriptan) tablets (Restricted Access on Basic Open and Basic Closed Formularies only)</td>
<td>Imitrex (sumatriptan) injection</td>
</tr>
<tr>
<td>Sumavel DosePro (sumatriptan) jet-injector</td>
<td>Imitrex STATdose (sumatriptan) auto-injector</td>
</tr>
<tr>
<td>Treximet (sumatriptan/naproxen) tablets</td>
<td>Maxalt and Maxalt MLT (rizatriptan) tablets</td>
</tr>
<tr>
<td>Zomig (zomitriptan) nasal solution</td>
<td>Zomig and Zomig ZMT (zomitriptan) tablets</td>
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</table>

For members on the Enhanced Formulary, before approval of a restricted access triptan is given, one non-restricted access triptan must be tried.
For members on the Basic Open Formulary, before approval of a restricted access triptan is given, up to two non-restricted access triptans must be tried.

For members on the Basic Closed Formulary, before approval of a non-formulary triptan is given, up to two formulary triptans must be tried.

**QUANTITY LIMIT EXCEPTION CRITERIA:**
Coverage is provided if:
1. Patient has the diagnosis of moderate to severe migraine headache, **AND**
2. Patient has tried and failed at least two of the following abortive migraine therapy drug classes:
   - NSAIDS/COX-2 Inhibitor (Ex. ibuprofen, naproxen, diclofenac, celecoxib, etc.)
   - Acetaminophen (Tylenol)
   - Ergotamine-containing products (Ex. Cafergot, Ergomar, etc.)
   - Isometheptene/dichloralphenazone/acetaminophen (Ex. Midrin, etc.) **AND**
3. If the patient experiences > 4 migraine headaches per month, prophylactic therapy (Ex. Amitriptyline, nortriptyline, topiramate, propranolol, divalproex) should have been given an adequate trial of at least 2 – 3 months, **AND**
4. The possibility of medication-induced, rebound or chronic daily headache has been considered and ruled out.

* Coverage of Axert is not provided for use in combination with another triptan (e.g. Zomig®, Imitrex®, Maxalt, Frova®, Relpax®) or an ergotamine (e.g. Migranal, Cafergot) due to the possibility of increased blood pressure effect.

**DOSAGE AND ADMINISTRATION:**
The almotriptan dose for the treatment of acute migraine in adults is 6.25 mg to 12.5 mg at migraine onset; the 12.5 mg dose may provide a greater effect for the acute treatment of migraines in adults. A second dose may be taken no sooner than 2 hours after the initial dose. Subsequent doses should be separated by not less than 2 hours. The total daily dose should not exceed 25 mg. The safety of using almotriptan to treat more than 4 migraine headaches in a 30-day period has not been established. **NOTE:** In patients who do not respond to the first dose of almotriptan, the diagnosis of migraine should be reconsidered before administration of a second dose and the possibility of an evolving cerebrovascular event considered.

**WARNINGS AND PRECAUTIONS:**
- Do not use with ergotamine-containing or ergot-type products or MAO-A inhibitors.
- Do not use in patients with ischemic heart disease or uncontrolled blood pressure.
- Do not use as a prophylactic agent.
- Give only where diagnosis of migraine is clearly established.
- Contraindications to the use of 5-HT1 agonists: pregnancy, peripheral vascular disease (i.e. thromboangitis, leutic arteritis, Raynaud’s Syndrome, thrombophlebitis, arteriosclerosis), hepatic or renal impairment, coronary artery disease, or uncontrolled hypertension.
**DRUG INTERACTIONS:**

- Ergot-containing drugs have been reported to cause prolonged vasospastic reactions. Because there is a theoretical basis that these effects may be additive, use of ergotamine-containing or ergot-type medications (like dihydroergotamine) and 5-HT1 agonists within 24 hours of each other should be avoided.
- MAO-A inhibitors increase the systemic exposure of the 5-HT1 agonists and concomitant use is contraindicated.
- Concomitant use of more than one 5-HT1 agonist within 24 hours of each other is not recommended.
- Selective serotonin reuptake inhibitors (SSRIs) have been reported to cause weakness, hyperreflexia, and incoordination when coadministered with 5-HT1 agonists.

**REFERENCES:**


**REFERENCES SUPPORTING AVERAGE NUMBER OF MIGRAINE ATTACKS PER MONTH:**

11. Eur Neurol 1996; 32 (suppl 2): 24-7 (n=606) – 2.9-3.2 per month.

**GENERAL REFERENCES:**


Last Revision Date: May 2015