BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/15/16
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AXERT® (almotriptan malate) oral tablet (brand and generic)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

AXERT® (almotriptan malate) oral tablet (brand and generic) (cont.)

Criteria:

- **Criteria for initial therapy:** Axert (brand) and almotriptan malate (generic) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. A confirmed diagnosis of **ONE** of the following:
     - Acute migraine attacks in an individual 18 years of age or older with a history of migraine with or without aura
     - Acute migraine headache pain in an individual 12 to 17 years of age with a history of migraine with or without aura, and who have migraine attacks usually lasting 4 hours or more (when untreated)
  2. Tried, failed or has contraindication to **ALL** of the following preferred triptans:
     - Naratriptan, rizatriptan, sumatriptan and zolmitriptan
  3. Uses and is adherent with **ONE** of the following migraine prophylactic medications:
     - Beta-blocker such as metoprolol, propranolol, or timolol
     - Antidepressant such as amitriptyline or venlafaxine
     - Anticonvulsant such as valproate or topiramate
     - Verapamil
  4. There are no contraindications
     - Contraindication include:
       - Ischemic heart disease, such as:
         - Angina pectoris
         - History of myocardial infarction
         - Documented silent ischemia
         - Coronary artery vasospasm
         - Prinzmetal's variant angina
         - Other significant underlying cardiovascular disease
       - Cerebrovascular syndromes such as:
         - Stroke
         - Transient ischemic attack (TIA)
       - Peripheral vascular disease including ischemic bowel disease
       - Uncontrolled hypertension
       - Use within 24 hours of an ergotamine-containing, or ergot-type medication (dihydroergotamine, ergotamine, methysergide)
       - Use within 24 hours of another triptan
       - Hemiplegic or basilar migraine
       - Known hypersensitivity to almotriptan or any of the inactive ingredients

  Initial approval duration: 8 tablets per month for 12 months

AXERT® (almotriptan malate) oral tablet (brand and generic) (cont.)

- **Criteria for continuation of coverage (renewal request):** Axert (brand) and almotriptan malate (generic) is considered ***medically necessary*** and will be approved with documentation of **ALL** of the following:

  1. The frequency of acute migraine attacks have decreased while on therapy
  2. Does not use acute migraine drugs more than 10 days a month
  3. Individual has been adherent with their migraine prophylactic medication
  4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use, such as:
     - Any of the contraindications listed above
     - Serotonin syndrome
     - Medication overuse headaches
  5. There are no significant interacting drugs

  Renewal duration: 8 tablets per month for 12 months

Description:

Axert (almotriptan) is indicated for the **acute treatment of migraine attacks in adults with a history of migraine with or without aura** and for the **acute treatment of migraine headache pain in adolescents age 12-17 years of age with a history of migraine with or without aura, who have migraine attacks usually lasting 4 hours or more (when untreated)**. In adolescents, age 12-17 years, efficacy of Axert (almotriptan) on migraine-associated symptoms such as nausea, photophobia, and phonophobia was not established. Axert (almotriptan) is not intended for prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine and it is not indicated for the treatment of cluster headache.

Migraine is a common episodic disorder, the hallmark of which is a disabling headache generally associated with nausea, and/or light and sound sensitivity. Migraine with aura refers to the occurrence of transient visual, sensory, language, or motor disturbance that is generally followed by a migraine headache. The exact mechanisms of migraine are unknown, but currently it is believed to initiate from a primary neuronal dysfunction that leads to a sequence of intracranial and extracranial changes accounting for migraine, including the four phases of premonitory symptoms, aura, headache and post-drome. Specifically, activation of the trigeminovascular system, cortical spreading depression, and neuronal sensitization all seem to play a role.

Selection of medication for treatment is directed mainly by the severity of the attacks, presence of associated nausea and vomiting, treatment setting, and patient-specific factors. Abortive treatments are usually more effective if they are given early in the course of the headache (within in the first hour if possible). The 2015 updated guideline assessment published by the American Headache Society lists the following medications as Level A (established as effective) for acute migraine treatment: all triptan drugs, combination of sumatriptan and naproxen, dihydroergotamine nasal spray, NSAIDs (naproxen, ibuprofen, aspirin, diclofenac), acetaminophen/aspirin/caffeine, and acetaminophen (for acute treatment of non-incapacitating migraine).

AXERT® (almotriptan malate) oral tablet (brand and generic) (cont.)

Almotriptan is a selective agonist for serotonin (also known as 5-hydroxytryptamine, 5-HT) receptors 1B and 1D located on intracranial blood vessels and sensory nerves of the trigeminal system. Activation of these receptors results in vasoconstriction of cranial vessels, inhibition of pro-inflammatory neuropeptide release by trigeminal nerves, and blockage of pain pathways in the brainstem. The medications in the "triptan" class include almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, and zolmitriptan. All of the triptans have been found to be effective for the treatment of acute migraine. Patients who do not respond well to one triptan may respond to another.

Resources:

Axert. Package Insert. Revised by manufacturer 8/2014. Accessed 07-29-2016.

Axert. Package Insert. Revised by manufacturer 05/2017. Accessed 08-22-2017, 07-19-2018.

Almotriptan. Package Insert. Revised by manufacturer 05/2017. Accessed 08-22-2017.

UpToDate: Acute treatment of migraine in adults. Current through Jul 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/acute-treatment-of-migraine-in-adults?source=search_result&search=acute%20migraine%20treatment&selectedTitle=1~150

UpToDate: Preventive treatment of migraine in adults. Current through Jul 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/preventive-treatment-of-migraine-in-adults?source=see_link

UpToDate: Acute treatment of migraine in children. Current through Jul 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/acute-treatment-of-migraine-in-children?source=search_result&search=acute%20migraine%20treatment&selectedTitle=2~150

UpToDate: Preventive treatment of migraine in children. Current through Jul 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/preventive-treatment-of-migraine-in-children?source=search_result&search=acute%20migraine%20treatment&selectedTitle=4~150

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.