Maxalt

Description

Maxalt / Maxalt-MLT (rizatriptan)

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: Maxalt is a serotonin (5-HT) 1B/1D receptor agonist (triptan) indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years of age (2).

Limitations of Use: (2)

1. Use only after clear diagnosis of migraine has been established.
2. Not indicated for the prophylactic therapy of migraine.

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 (MOH) (2).

Maxalt is contraindicated in patient with: history of ischemic coronary artery disease or other significant underlying cardiovascular disease, history of coronary artery vasospasm, history of stroke or transient ischemic attack, peripheral vascular disease, ischemic bowel disease, uncontrolled hypertension, recent use (within 24 hours) of another 5HT1 agonist, ergotamine-containing medication, hemiplegic or basilar migraine, concurrent use or recent discontinuation (within 2 weeks) of a MAO-I inhibitor, and hypersensitivity to Maxalt or Maxalt-MLT (2).

Related policies
Amerge, Axert, Butalbital analgesics, Frova, 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.

Maxalt may be considered medically necessary in adults and pediatric patients between the ages of 6 and 17 for the treatment of migraine with or without aura and if the conditions indicated below are met.

Maxalt is considered investigational in patients less than 6 years of age and for all other indications.

Prior-Approval Requirements

Age 6 years of age or older

Diagnoses

Patient must have ONE of the following:

1. Migraine, with aura (classic)
2. Migraine, without aura (common)

AND NONE of the following:
1. Hemiplegic migraine
2. Basilar migraine
3. Dual therapy after 6 months of calcitonin gene related peptide (CGRP) antagonist therapy
4. Dual therapy with Reyvow (lasmiditan)
5. Another PA on file for any triptan agent

Prior – Approval Renewal Requirements
Same as above

Policy Guidelines

Pre - PA Allowance

<table>
<thead>
<tr>
<th>Age</th>
<th>18 years of age or older</th>
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<tbody>
<tr>
<td>6 - 17 years of age</td>
<td>no pre-PA allowance</td>
</tr>
</tbody>
</table>

| Quantity |
|---------------------|------------------|
| **Strength** | **Quantity** |
| 5 mg | 72 tablets per 90 days OR |
| 10 mg | 36 tablets per 90 days |

Prior - Approval Limits

<table>
<thead>
<tr>
<th>Age</th>
<th>18 years of age or older</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 - 17 years of age</td>
<td></td>
</tr>
</tbody>
</table>

| Quantity |
|---------------------|------------------|
| **Strength** | **Quantity** |
| 5 mg | 108 tablets per 90 days OR |
| 10 mg | 54 tablets per 90 days |

Age | 6 - 17 years of age |
Quantity |  |

<table>
<thead>
<tr>
<th>Strength</th>
<th>Weight</th>
<th>Concurrent Propranolol</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 mg</td>
<td>≥ 40 kg</td>
<td>No</td>
<td>38 tablets per 90 days OR</td>
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</table>
**Duration**  
6 months

**Prior – Approval Renewal Limits**  
Same as above

**Rationale**

**Summary**
Maxalt is indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years of age. Maxalt is not indicated for the prophylactic therapy of migraine or the treatment of cluster headaches. 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).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Maxalt while maintaining optimal therapeutic outcomes.

**References**


**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2012</td>
<td>Age limitation revision to include 6-17 years of age</td>
</tr>
<tr>
<td>September 2012</td>
<td>Changed quantity limit to 1.5 x FDA-approved dosage</td>
</tr>
<tr>
<td>December 2012</td>
<td>Annual review and update</td>
</tr>
</tbody>
</table>
Section: Prescription Drugs
Subsection: Analgesics and Anesthetics
Effective Date: January 1, 2020
Original Policy Date: September 8, 2011
Subject: Maxalt
Page: 5 of 5

September 2014  Annual editorial review and reference update
June 2015  Annual editorial review and reference update
March 2016  Annual editorial review and reference update
March 2017  Annual review and reference update
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

Keywords

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