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| **Section:** | Prescription Drugs | **Effective Date:** | January 1, 2025 |
| **Subsection:** | Analgesics and Anesthetics | **Original Policy Date:** | September 8, 2011 |
| **Subject:** | Maxalt | **Page:** | 1 of 6 |

***Last Review Date:*** December 13, 2024

# 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-$HT_1$ 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: 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.

3. 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 (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**
5-HT1 Agonists, Butalbital analgesics, Dihydroergotamine Nasal Sprays, Elyxyb, Migraine CGRP Antagonists IV, Migraine CGRP Antagonists Nasal, Migraine CGRP Antagonists Oral, Migraine CGRP Antagonists SC, Migraine Powders

## 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** if the conditions indicated below are met.

Maxalt may be considered **investigational** 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 ALL** of the following:

a. Patient is currently using migraine prophylactic therapy **OR** the patient has had an inadequate treatment response, intolerance, or contraindication to migraine prophylactic therapy (e.g., divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, etc.)
b. **NO** hemiplegic migraine
c. **NO** basilar migraine
d. **NO** dual therapy with a calcitonin gene related peptide (CGRP) antagonist for acute migraine treatment (e.g., Nurtec ODT, Ubrelvy)
e. **NO** dual therapy with Reyvow (lasmiditan) or Elyxyb (celecoxib)
f. **NO** other PA on file for any triptan agent

## Prior – Approval *Renewal* 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 ALL** of the following:

a. **NO** hemiplegic migraine
b. **NO** basilar migraine
c. **NO** dual therapy with a calcitonin gene related peptide (CGRP) antagonist for acute migraine treatment (e.g., Nurtec ODT, Ubrelvy)
d. **NO** dual therapy with Reyvow (lasmiditan) or Elyxyb (celecoxib)
e. **NO** other PA on file for any triptan agent

## Policy Guidelines

## Pre - PA Allowance

**Age** 18 *years of age or older*
*No Pre-PA Allowance for under 18 years of age*

**Quantity**

- Patients are allowed Pre-PA quantities of up to **TWO** triptan medications **only.**

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

## Prior - Approval Limits

**Age** *18 years of age or older*

**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**

| Strength | Weight | Concurrent Propranolol | Quantity |
|---|---|---|---|
| 5 mg | < 40 kg | **No** | 18 tablets per 90 days **OR** |
| 5 mg | **≥** 40 kg | **No** | 38 tablets per 90 days **OR** |
| 10 mg | < 40 kg | **No** | **Excluded** |
| 10 mg | **≥** 40 kg | **No** | 18 tablets per 90 days |
| | | | |
| 5 mg | < 40 kg | **Yes** | **Excluded** |
| 5 mg | **≥** 40 kg | **Yes** | 18 tablets per 90 days |
| 10 mg | < 40 kg | **Yes** | **Excluded** |
| 10 mg | **≥** 40 kg | **Yes** | **Excluded** |

**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**

1. Serotonin 5-HT1 Receptor Agonists (Triptans). Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; December 2017.
2. Maxalt / Maxalt-MLT [package insert]. Jersey City, NJ: Organon LLC; June 2021.

## Policy History

| Date | Action |
|---|---|
| April 2012 | Age limitation revision to include 6-17 years of age |
| September 2012 | Changed quantity limit to 1.5 x FDA-approved dosage |
| December 2012 | Annual review and update |
| September 2014 | Annual editorial review and reference update |
| June 2015 | Annual editorial review and reference update |
| March 2016 | Annual editorial review and reference update<br>Policy code changed from 5.02.16 to 5.70.16 |
| 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 |
| March 2020 | Annual review and reference update |

| | |
|---|---|
| June 2020 | Annual review |
| April 2021 | Added no dual therapy with a CGRP antagonist for acute migraine treatment. Revised no dual therapy requirement after 6 months of a prophylactic CGRP antagonist. Added initiation requirement to be on a migraine prophylactic therapy or have an inadequate treatment response, intolerance, or contraindication to migraine prophylactic therapy |
| June 2021 | Annual review and reference update |
| September 2021 | Annual review and reference update |
| March 2022 | Annual review. Per SME, removed requirement of “no dual therapy after 6 months with a prophylactic CGRP antagonist” |
| April 2022 | Added no dual therapy with Elyxyb. Added Pre-PA quantity statement that patients are allowed Pre-PA for two triptan medications only |
| June 2022 | Annual review |
| June 2023 | Annual review. Changed policy number to 5.70.016 |
| September 2023 | Annual review |
| June 2024 | Annual review and reference update |
| December 2024 | Annual review |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.**