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5.70.016

Section:	Prescription Drugs	**Effective Date:**	October 1, 2023
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	September 8, 2011
Subject:	Maxalt	**Page:**	1 of 6

Last Review Date: September 8, 2023

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]. Whitehouse Station, NJ: Merck & Co., Inc.; September 2020.

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 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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.