

MAXALT® UTILIZATION MANAGEMENT CRITERIA

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|------------------------------|---------------------------|---|
| DRUG CLASS: | 5HT ₁ agonists | HICL = 00000000016535 |
| BRAND (generic) NAME: | Maxalt (rizatriptan) | 5 mg tablet (GCN = 019591), 10 mg tablet (GCN = 019592) |
| | Maxalt-MLT (rizatriptan) | 5 mg orally disintegrating tablet (GCN = 019593) |
| | | 10 mg orally disintegrating tablet (GCN = 019594) |

FDA INDICATIONS: Oral rizatriptan 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.

ICD-9 CODES:

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|--|-------|
| Migraine – with aura (“classic”): | 346.0 |
| Migraine – idiopathic/without aura (“common”): | 346.1 |

QUANTITY LIMITATIONS (QL) CRITERIA:

| | SHORT TERM: | EXTENDED SUPPLY: |
|------------------|---------------------------|---------------------------|
| | 120 mg per 30 days | 360 mg per 90 days |
| Maxalt 10 mg | 12 | 36 |
| Maxalt 5 mg | 24 | 72 |
| Maxalt-MLT 10 mg | 12 | 36 |
| Maxalt-MLT 5 mg | 24 | 72 |

If patient is requiring amounts in excess of these numbers, please follow the Quantity Limitations (QL) criteria developed for Maxalt and Maxalt-MLT.

RATIONALE: Maxalt and Maxalt-MLT (rizatriptan) tablets – Rizatriptan has a maximum dose of 30 mg per day. Merck has studied rizatriptan in up to 4 migraines per month, or 120 mg per month. Rizatriptan is packaged in boxes of 6, so 2 boxes of 10 mg tablets should last one month.

CRITERIA FOR EXCEEDING QL:

1. Convey to physician the amount of the drug that the patient has already received (refer to QL criteria) and ask if the patient needs more than that amount. **AND**
2. Patient must have diagnosis of moderate to severe migraine headache. (Tension type and chronic daily headaches are **NOT** appropriate diagnoses.) **AND**
3. Must have tried and failed at least 2 other abortive migraine therapy. Examples of medications used for abortive therapy include:
 - Ibuprofen (Motrin®)
 - Diclofenac (Voltaren®)
 - Flurbiprofen (Ansaid®)
 - Ergotamine-containing products (Cafergot, Wigraine, Ergomar, etc.)
 - Isometheptene mucate/Dichloralphenazone/Acetaminophen (Midrin, etc.) **AND**
4. If patient experiences > 4 migraine headaches per month, prophylactic therapy should have been given an adequate trial (see table below) **AND**
5. The possibility of medication-induced, rebound, or chronic daily headache should be considered. **AND**
6. **DENY** if to be used in combination with another triptan (e.g. Zomig, Amerge, Imitrex, Axert, Frova, Relpax) or an ergotamine (e.g. Migranal, Cafergot) due to possibility of increased blood pressure effect.



BLACK BOX WARNINGS:

None

RATIONALE:

- Aspirin, acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs) and combination products containing these key ingredients are generally considered first line abortive therapy for migraine.
- Prophylactic migraine therapy may reduce the frequency and severity of migraine attacks.
- Quantity limitations criteria are intended to prevent inappropriate use of the triptans.

NURSING ASSESSMENT:

1. Gather a complete medical history; note any contributing factors (i.e. smoker, diet, alcohol consumption, use of OTC medications, stress, etc.). Include migraine history and any precipitating factors.
2. Determine any history of cardiac problems or evidence of ischemic cardiovascular disease, as drug is contraindicated.
3. Ensure that a neurological examination has been performed to identify appropriate migraine category.
4. Obtain baseline ECG, liver (AST, ALT), and renal function tests.

PROVIDER EDUCATION:

1. Review appropriate method for administration (oral).
2. Nausea, vomiting, malaise, and fatigue are the most common adverse effects.
3. Phenylketonuric patients should be informed that Maxalt-MLT orally disintegrating tablets contain phenylalanine (a component of aspartame). Each 5 mg disintegrating tablet contains 1.05 mg of phenylalanine, and each 10 mg disintegrating tablet contains 2.10 mg of phenylalanine.
4. Merck and Co. Drug Information: 800-672-6372.

MISUSE AND CHRONIC DAILY HEADACHE:

“Chronic Daily Headache (CDH) is a syndrome that consists of a group of disorders that can be subclassified into primary and secondary types. Drug-induced daily headache frequently arises during headache therapy. It can result from the daily use of ergotamines and excessive amounts of common analgesics. CDH usually manifests itself as a constant dull pressure in the frontal and occipital areas. Most patients will complain of headache upon awakening in the morning. The symptomatic medications used for the immediate relief of headache may actually perpetuate the headache if used frequently and in excessive quantities. Therapy for drug-induced headache is withdrawal of the responsible medication.”

CLINICAL OUTCOME:

Reversal of acute migraine attack and relief of associated symptoms.

DOSAGE AND ADMINISTRATION:

In controlled clinical trials, single doses of 5 and 10 mg of rizatriptan were effective for the acute treatment of migraines in adults. There is evidence that the 10 mg dose may provide a greater effect than the 5 mg dose. Individuals may vary in response to doses of rizatriptan, so the choice of dosage should be made on an individual basis. Patients taking concomitant propranolol (Inderal®) should take rizatriptan 5 mg. Doses should be separated by 2 hours with a maximum dose of 30 mg in a 24 hour period. For Maxalt-MLT orally disintegrating tablets, administration with liquids is not necessary. The orally disintegrating tablet is packaged in a blister within an outer aluminum pouch. Patients should be instructed not to remove the blister from the outer pouch until just prior to dosing. The blister pack should then be peeled open with dry hands and the orally disintegrating tablet placed on the tongue, where it will dissolve and be swallowed with the saliva.

RISK FACTORS/CONTRAINDICATIONS:

1. Do not use with ergotamine-containing products or MAO-A inhibitors.
2. Do not use with patients with ischemic heart disease or uncontrolled blood pressure.
3. Do not use as a prophylactic agent.
4. Give only where diagnosis of migraine is clearly established.
5. Contraindications to the use of 5-HT₁ agonists: pregnancy, peripheral vascular disease (i.e., thromboangitis, leitic arteritis, Raynaud's Syndrome, thrombophlebitis, arteriosclerosis), hepatic or renal impairment, coronary artery disease, 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.
- Propranolol (Inderal®) increases rizatriptan plasma concentrations by 70%. Patients taking concomitant propranolol should take rizatriptan 5 mg.
- Selective serotonin reuptake inhibitors (SSRIs) have been reported to cause weakness, hyperreflexia, and in coordination when coadministered with 5-HT₁ agonists.

MIGRAINE THERAPY OPTIONS:

Examples of Prophylactic therapy for migraine headache (this list may not be complete). An adequate trial of 2-3 months of treatment should be given before drug considered ineffective:

| DRUG CLASS | NAME |
|-----------------------------------|---|
| • Beta Blockers | Propranolol Atenolol Metoprolol Timolol |
| • Antidepressants | Amitriptyline Fluoxetine |
| • Calcium Channel Blockers | Nifedipine Verapamil Diltiazem |
| • Anticonvulsants | Divalproex sodium/sodium valproate Carbamazepine Gabapentin Topiramate |
| • NSAIDs | Naproxen Aspirin Ketoprofen |
| • Other | Feverfew Magnesium Vitamin B2 (Riboflavin) |

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