

ZOMIG® UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	5HT ₁ agonists
BRAND NAME:	Zomig 2.5 mg oral tablet
(Generic)	(zolmitriptan) 5 mg oral tablet
	5 mg nasal spray
	Zomig ZMT 2.5 mg orally disintegrating tablet
	(zolmitriptan) 5 mg orally disintegrating tablet

FDA INDICATIONS:

Oral zolmitriptan 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:

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

QL CRITERIA:

	<u>Short Term:</u> 40 mg per 30 days	<u>Extended Supply:</u> 120 mg per 90 days
Zomig ZMT 2.5mg	16 tablets	48 tablets
Zomig ZMT 5mg	8 tablets	24 tablets
Zomig tablets 2.5mg	16 tablets	48 tablets
Zomig tablets 5mg	8 tablets	24 tablets
Zomig 5mg Nasal Spray	8 units	24 units

If patient is requiring amounts in excess of these limits, please follow the Quantity Limitations (QL) criteria developed for Zomig.

RATIONALE:

Zomig (zolmitriptan) – The maximum daily dose of Zomig is 10 mg, and can be used in up to 4 migraine headaches per month, or 40 mg per month.

CRITERIA FOR EXCEEDING QUANTITY LIMITATIONS:

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 be considered (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., Imitrex, Amerge, Maxalt, 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 the 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. AstraZeneca Pharmaceuticals Information Center: 800-236-9933

MISUSE AND CHRONIC DAILY HEADACHE:

Chronic Daily Headache (CDH) is a syndrome that consists of a group of disorders that can be sub-classified 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 manifest itself as a constant dull pressure in the frontal and occipital areas. Most of the 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 of 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 1, 2.5 and 5 mg tablets and 5 mg nasal spray were effective for the acute treatment of migraine in adults. In the trials for the tablet formulation, a greater proportion of patients had headache response following a 2.5 or 5 mg dose than following a 1 mg dose. In the only direct comparison of 2.5 and 5 mg tablets, there was little added benefit from the larger dose but side effects were generally increased at 5 mg. Patients should, therefore, be started on 2.5 mg tablets or lower. A dose lower than 2.5 mg can be achieved by manually breaking a 2.5 tablet in half. If the headache returns after an initial dose with tablets or nasal spray, the dose may be repeated after 2 hours, not to exceed 10 mg within a 24-

hour period. Controlled trials have not adequately established the effectiveness of a second dose if the initial dose is ineffective.

RISK FACTORS/CONTRAINDICATIONS:

1. Do not use with ergotamine-containing products or MAO-A inhibitors.
2. Do not use in 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, leutic arteritis, Raynaud’s Syndrome, thrombophlebitis, arteriosclerosis), hepatic or renal impairment, severe itching, 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.
- Selective serotonin reuptake inhibitors (SSRIs) have been reported to cause weakness, hyperreflexia, and incoordination when coadministered with 5-HT₁ agonists.

Migraine therapy options:

Table Prophylactic therapy for migraine headache

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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REFERENCES:

1. Zomig (zolmitriptan) package insert. AstraZeneca Pharmaceuticals, Wilmington, Delaware. January 2007

2. Snow V, Weiss K, Wall EM et al. Pharmacologic Management of Acute Attacks of Migraine and Prevention of Migraine Headache. *Annals of Internal Med.* 2002;137(10):840-849.
3. Silberstein SD et al. "Practice Parameter: Evidence based guidelines for migraine headache (an evidence-based review). Report on the Quality Standards Subcommittee of the American Academy of Neurology." *Neurology* 2000;55:754-63.
4. Seema M and Lowder DM. Medications for Migraine Prophylaxis. *Am Fam Physician* 2006;73:72-8.
5. Drugdex editorial staff. *Micromedex Inc.* Volume 92, 1997.
6. Edmeads JG, Gawel MJ, Vickers J. Strategies for diagnosing and managing medication-induced headache. *Can Fam Physician.* 1997; 43: 1249-1254.
7. Mathew NT. Transformed migraine, analgesic rebound, and other chronic daily headaches. *Neurologic Clinics.* 1997; 15 (1): 167-186.
8. Moore KL, Noble SL. Drug treatment of migraine: Part I. Acute therapy and drug-rebound headache. *Am Fam Physician.* 1997; 56 (8): 2039-2048.
9. Edmeads J. Headaches in older people. *Postgrad Med.* 1997: 101 (5): 91-100.
10. PDR Nurse's handbook; 3rd edition. 1998
11. Saunders' Nursing Drug handbook; W.B. Saunders Co., 1999.