

**AMERGE®
UTILIZATION MANAGEMENT CRITERIA**

DRUG CLASS:	5HT ₁ agonists	
BRAND NAME:	Amerge	2.5 mg oral tablet
(Generic)	(naratriptan)	1 mg oral tablet

FDA INDICATIONS:

Oral naratriptan 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

<u>QL CRITERIA:</u>	<u>Short Term:</u>	<u>Extended Supply:</u>
Amerge 2.5 mg	23 mg per 30 days	69 mg per 90 days
Amerge 1 mg	1 pack (9 tablets)	3 packs (27 tablets)
	23 tablets	69 tablets
<i>If patient is requiring amounts in excess of these numbers, please follow the Quantity Limitations (QL) criteria developed for Amerge.</i>		

RATIONALE:

Amerge (naratriptan) tablets - Naratriptan has a maximum dose of 5 mg per day. Glaxo has studied naratriptan in up to 4 migraines per month, or 20 mg per month. Naratriptan is packaged in boxes of 9, so 1 box of 2.5 mg tablets should last one 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., Zomig, Imitrex, 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 (e.g., smoker, 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. Glaxo SmithKline Drug Information: 800-334-0089

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 and 2.5 mg of naratriptan taken with fluid were effective for the acute treatment of migraine in adults. A greater proportion of patients had headache response following a 2.5 mg dose than following a 1 mg dose. Individuals may vary in response to doses of Amerge. The choice of dose, therefore, should be made on an individual basis, weighing the possible benefit of the 2.5 mg with the potential for a greater risk of adverse events. If the headache returns, or if the patient has only partial response, the dose may be repeated once after 4 hours, for a maximum dose of 5 mg in a 24-hour period. There is evidence that doses of 5 mg do not provide a greater effect than doses of 2.5 mg.

The dosage and administration section of the prescribing information for Amerge Tablets states, “The safety of treating, on average, more than four headaches in a 30 day period has not been established. This statement is based on experience from an open-labeled, long-term study designed to evaluate the safety of using Amerge Tablets over a 12-month period. The average number of attacks treated was four per month. The number of doses taken per attack averaged 1.3 indicating that the majority of patients required a single dose of Amerge to treat the attack. However, some patients may require a second dose.”

RISK FACTORS/CONTRAINDICATIONS:

1. Do not use with ergotamine-containing or ergot-type 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, leuetic arteritis, Raynaud's Syndrome, thrombophlebitis, arteriosclerosis), hepatic or renal impairment, coronary artery disease (CAD), 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 in coordination when co-administered 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)

Initial Date: January 1999

Review Date: 9/2007

REFERENCES:

1. Amerge (naratriptan) package insert. Glaxo SmithKline, Inc., Research Triangle Park, NC. April 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. Data on File, Glaxo SmithKline Inc.
11. PDR Nurse's Handbook; 3rd edition. 1998.
12. Saunders' Nursing Drug Handbook; W.B. Saunders Co., 1999.