



## MIGRAINE THERAPY QUANTITY LIMITS

### Preauthorization Criteria for Approval

#### Medications and Dosage Forms Included in Criteria

Generic Name	Brand Name	Dosage Form
Almotriptan malate	Axert <sup>®</sup>	Oral tablets
Butorphanol tartrate <sup>†</sup>	Stadol NS <sup>®*</sup>	Nasal spray
Dihydroergotamine mesylate <sup>†</sup>	D.H.E. 45 <sup>®</sup>	Injection
Dihydroergotamine mesylate	Migranal <sup>®</sup>	Nasal spray
Eletriptan hydrobromide	Relpax <sup>®</sup>	Oral tablets
Ergotamine tartrate	Ergomar <sup>®</sup>	Sublingual tablets
Ergotamine tartrate/caffeine <sup>†</sup>	Cafergot <sup>®</sup>	Oral tablets
Ergotamine tartrate/caffeine	Migergot <sup>®</sup>	Rectal suppositories
Frovatriptan succinate	Frova <sup>®</sup>	Oral tablets
Naratriptan hydrochloride	Amerge <sup>®</sup>	Oral tablets
Rizatriptan benzoate	Maxalt <sup>®</sup> Maxalt-MLT <sup>®</sup>	Oral tablets Orally disintegrating tablets
Sumatriptan	Imitrex <sup>®</sup>	Oral tablets, injection, nasal spray
Sumatriptan/naproxen sodium	Treximet <sup>™</sup>	Oral tablet
Zolmitriptan	Zomig <sup>®</sup> Zomig-ZMT <sup>®</sup>	Oral tablets, injection Orally disintegrating tablets

<sup>†</sup> Generic products available

\* Brand name no longer available

### FDA Approved Indications<sup>1-17</sup>

**Amerge (Naratriptan)**

**Axert (almotriptan)**

**Frova (frovatriptan)**

**Imitrex Nasal Spray (sumatriptan)**

**Imitrex tablets (sumatriptan)**

**Maxalt (rizatriptan)**

**Maxalt-MLT(rizatriptan)**

**Relpax (eletriptan)**

**Zomig (zolmitriptan)**

**Zomig Nasal Spray (zolmitriptan)**

**Zomig-ZMT (zolmitriptan)**

Indicated for the acute treatment of migraine with or without aura in adults. They are not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness have not been established for cluster headache, which is present in an older, predominantly male population.

#### **Imitrex Injection (sumatriptan)**

Indicated for 1) the acute treatment of migraine attacks with or without aura and 2) the acute treatment of cluster headache episodes. The injection is not for use in the management of hemiplegic or basilar migraine.

**Treximet (sumatriptan/naproxen sodium)**

Indicated for the acute treatment of migraine with or without aura in adults. Carefully consider the potential benefits and risks of Treximet and other treatment options when deciding to use the Treximet. Treximet is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness has not been established for cluster headache.

**Cafergot tablets (ergotamine tartrate/caffeine)**

**Ergomar sublingual tablets (ergotamine tartrate)**

**Migergot rectal suppositories (ergotamine tartrate/caffeine)**

Indicated as therapy to abort or prevent vascular headache, e.g., migraine, migraine variants, or so-called "histaminic cephalalgia".

**Migranal Nasal Spray (dihydroergotamine mesylate)**

Indicated for the acute treatment of migraine headaches with or without aura. Migranal is not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.

**D.H.E. 45 injection (dihydroergotamine mesylate)**

Indicated for the acute treatment of migraine headaches with or without aura and the acute treatment of cluster headache episodes.

**Stadol NS (butorphanol tartrate nasal spray)**

Indicated for the management of pain when the use of an opioid analgesic is appropriate.

**Description**

The Migraine Therapy Quantity Limit program is designed to allow patients needing acute migraine treatment based on therapy guidelines, practice parameters, and package labeling. Patients using quantities under the quantity limits set by the criteria do not need preauthorization (PA) to obtain prescription medications as their prescription claims will properly adjudicate. The PA criteria is utilized to allow approval for quantities above the maximum monthly quantity limits recommended in product labeling for specific situations upon PA evaluation. The criteria is based on current guidelines and practice parameters to assist in the treatment and prevention of migraine headaches and requires a diagnosis of migraine headache to fulfill the approved indications provided in the product labeling.

**Table – Migraine Therapy Quantity Limits<sup>1-17</sup>**

Medication	Strength/ Formulation	How Supplied	Maximum 24-hour Dose	Quantity Limit (per 30 day supply)
Amerge®	1 mg tablets	9 tablet blister pack	5 mg	12 tablets
	2.5 mg tablets	9 tablet blister pack		
Axert®	6.25 mg tablets	6 tablet blister pack	25 mg	12 tablets
	12.5 mg tablets	12 tablet blister pack		
Butorphanol Nasal Spray	10 mg/mL nasal spray	2.5 mL (10 mg/mL) canister	2 mg q 3-4 h	3 canisters
Cafergot®	1 mg ergotamine tartrate/ 100 mg caffeine tablets	100 tablets/bottle	6 tablets (10 tablets/week)	40 tablets
D.H.E. 45®	1 mg/mL injection	1 mL ampules (10/package)	2 mg IV; 3 mg IM, SC (6 mg/week)	20 ampules
Ergomar®	2 mg sublingual tablets	20 tablets (5, 2x2 foil strips)	6 mg (10 mg/week)	40 tablets
Frova®	2.5 mg tablets	9 tablet blister card	7.5 mg	12 tablets
Imitrex®	4 mg STATdose System®	2 single-doses/package	12 mg	12 doses (6 packages)
	4 mg STATdose refills	2 single-doses/package		12 doses (6 packages)
	6 mg STATdose System®	2 single-doses/package		12 doses (6 packages)
	6 mg STATdose refills	2 single-doses/package		12 doses (6 packages)
	6 mg/0.5 mL single-dose vial	5 x 0.5 mL vials/pkg		5 mL (2 packages)
	5 mg nasal spray	6 sprays/package	40 mg	12 units (2 packages)
	20 mg nasal spray	6 sprays/package		12 units (2 packages)
	25 mg tablets	9 tablet blister pack	200 mg	12 tablets
	50 mg tablets	9 tablet blister pack		12 tablets
100 mg tablets	9 tablet blister pack	12 tablets		
Maxalt®	5 mg tablets	12 tablets/carton	30 mg	12 tablets
	10 mg tablets	12 tablets/carton		12 tablets
	5 mg MLT tablets	4 x 3-tablet blister pack		12 tablets
	10 mg MLT tablets	4 x 3-tablet blister pack		12 tablets
Migergot®	rectal suppositories	12 suppositories/box	2 suppositories (5 supp/week)	20 suppositories
Migranal®	Nasal Spray – 1 mL vial (Each vial contains 4 mg/1ml – 0.5 mg per spray)	8 units (1 mL/unit)/package	3 mg (4 mg/week)	16 mL (2 packages)
Relpax®	20 mg tablets	6 tablet blister pack	80 mg	12 tablets
	40 mg tablets	6 tablet blister pack		12 tablets
	40 mg tablets	2, 6 tablet blister packs		12 tablets
Treximet™	Sumatriptan 85 mg/ naproxen 500mg tablets	9 tablet compact	2 tablets	9 tablets
Zomig®	5 mg/100 µL nasal spray	6 unit dose spray units/pkg	10 mg	12 nasal spray units
	2.5 mg tablets	6 tablet blister pack		12 tablets
	5 mg tablets	3 tablet blister pack		12 tablets
	2.5 mg ZMT tablets	6 tablet blister pack		12 tablets
	5 mg ZMT tablets	3 tablet blister pack		12 tablets

## Criteria

### Triptans

**(Amerge, Axert, Frova, Imitrex, Maxalt, Maxalt-MLT, Relpax, Treximet, Zomig, Zomig-ZMT)**

- Does the patient need more medication than the determined limit of the requested agent?  
If yes, continue to 2.  
If no, medication does not require preauthorization.
- Does the patient have a diagnosis of migraine headache? (Note: stress, tension, and muscle contraction headaches are NOT appropriate diagnoses)  
If yes, continue to 3.  
If no, continue to 5.

3. Has the patient been prescribed more than one of the following drugs in the past 90 days: Amerge, Axert, Frova, Imitrex, Maxalt, Maxalt-MLT, Relpax, Treximet, Zomig, Zomig-ZMT, Cafergot, D.H.E. 45, Migranal, Ergomar, dihydroergotamine mesylate injection USP, Migergot, ergotamine/caffeine, Stadol NS, or butorphanol tartrate nasal spray?  
If yes, deny (further review required).  
If no, continue to 4.
4. Is the patient currently taking, or has the patient tried and failed prophylactic therapy?  
If yes, approve for the requested amount up to 1.5 times the quantity limit for 12 months.  
(Note: Further review is necessary if the request is for more than 1.5 times the quantity limit of the requested agent)  
If no, deny (further review required).
5. Has the patient been prescribed Imitrex injection for the treatment of cluster headache?  
If yes, approve Imitrex injection for quantity requested up to 1.5 times the quantity limit for 12 months.  
(Note: Further review is necessary if the request is for more than 1.5 times the quantity limit of the requested agent)  
If no, deny.

**Butorphanol tartrate nasal spray (Stadol NS)**

1. Does the patient need more medication than 3 canisters or 9 mL per 30 day supply?  
If yes, deny.  
If no, medication does not require preauthorization.

**Ergotamine, Ergot Combinations, and dihydroergotamine (Cafergot, Migergot, ergotamine tartrate/caffeine, Ergomar, Migranal, D.H.E. 45, dihydroergotamine mesylate injection USP)**

7. Does the patient need more medication than the limit provided in the Migraine Therapy Quantity Limits table?  
If yes, deny.  
If no, medication does not require preauthorization.

**Rationale**

The effectiveness of long-term therapy in the management of patients with migraine headaches is often difficult due to complexity of the disease. In its complexity, long-term goals of migraine management are to reduce attack frequency and severity, reduce disability, improve quality of life, prevent headache, avoid headache medication escalation, and educate and enable patients to manage their disease.<sup>18</sup> The American Academy of Neurology (AAN) has published evidence-based practice guidelines and parameters to assist in the management of migraine headaches.<sup>18,19</sup> Both published guidelines recommend “limiting acute therapy for patients who have more than two headache days per week on a regular basis.”<sup>18,19</sup> Patients escalating their dose of acute medications may risk developing medication-overuse headaches (e.g., rebound headache or drug-induced headache).<sup>18,19</sup>

Patients that develop medication-overuse headaches or are escalating their dosing of acute medications are recommended by current guidelines to use preventative therapy.<sup>18-20</sup> Medication-overuse headaches are usually aggravation of the primary headache (e.g., migraine headache) and usually arise in those patients that have frequently and chronically used acute medications, including analgesics.<sup>21,22</sup> According to the new classification of medication-overuse headache as a secondary headache, the diagnosis of these headaches are based on having a headache 15 or more days per month and the headache recedes after withdrawal. The medication frequency has been defined in the diagnosis criteria as taking triptans, ergots, and opioids on 10 or more days per month or utilizing analgesics 15 days of more per month over at least 3 months.<sup>21,22</sup>

Health care providers should work with their patients to manage their migraine headaches and determine if preventative therapy is warranted. Preventative therapy should be strongly considered if use of acute

medication escalates or the patient has five or more headaches per month.<sup>23</sup> In general, two-thirds of the patients started on preventative medications have a 50% reduction in the frequency of their headaches.<sup>23</sup>

Survey's conducted over time have consistently found a median frequency of migraine attacks at 1.5 per month and last for approximately 24 hours.<sup>24-28</sup> Based on these results, the limits provided within the Migraine Therapy Quantity Limits are set to accommodate two times the median frequency of attacks (3 migraines) and two times the median attack duration (2 days). Accordingly, these limits provide six days of migraine headaches per month without preauthorization. The preauthorization process is in place to evaluate patients requesting more medication per month than allowed in the Migraine Therapy Quantity Limits table on page 2.

Cluster headache is defined by the International Headache Society as "attacks of severe, strictly unilateral pain which is orbital, supraorbital, temporal or in any combination of these sites, lasting 15-180 minutes and occurring from once every other day to 8 times a day."<sup>29</sup> These headaches are accompanied by at least one of the following: ipsilateral conjunctival injection and/or lacrimation, ipsilateral nasal congestion and/or rhinorrhoea, ipsilateral eyelid oedema, ipsilateral forehead and facial sweating, ipsilateral miosis and/or ptosis, a sense of restlessness or agitation.<sup>29</sup> Treatment of cluster headaches relies on abortive and prophylactic medications.<sup>30-32</sup> The treatment of choice for abortive therapy is oxygen and/or sumatriptan injection.<sup>30-32</sup> The use of oral triptans are not suitable based on the quick and short duration of cluster headaches and the time needed to systemically absorb oral medications.<sup>32</sup> Prophylactic therapy can include verapamil, lithium, topiramate, valproic acid, or melatonin.<sup>30-32</sup> Prophylactic therapy is generally used long-term to maximize efficacy and to decrease the frequency of cluster headache.<sup>30-32</sup>

The basis for the Migraine Therapy Quantity Limit Table follows.

### **Triptans<sup>1-11</sup>**

#### **Amerge**

In controlled clinical trials, single doses of 1 and 2.5 mg tablets taken with fluid were effective for the acute treatment of migraines 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 treatment. The choice of dose should therefore be made on an individual basis, weighing the possible benefit of the 2.5 mg dose 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 2.5 mg. The safety of treating, on average, more than 4 headaches in a 30-day period has not been established.

The quantity limit is set at 12 of the 1 or 2.5 mg tablets. This limit allows for the treatment of 6 daily dose migraine days per month and also allows for the restriction of utilizing more than the maximum daily dose of 5 mg for 6 migraine days per month.

#### **Axert**

In controlled clinical trials, single doses of 6.25 and 12.5 mg tablets were effective for the acute treatment of migraines in adults, with the 12.5 mg dose tending to be a more effective dose. Individuals may vary in response to treatment. The choice of dose should therefore be made on an individual basis. If the headache returns, the dose may be repeated after 2 hours, but no more than two doses should be given within a 24-hour period. Controlled trials have not adequately established the effectiveness of a second dose if the initial dose is ineffective. The safety of treating an average of more than four headaches in a 30-day period has not been established.

The quantity limit is set at 12 of the 6.25 or 12.5 mg tablets. This limit allows for the treatment of 6 daily dose migraine days per month and also allows for the restriction of utilizing more than the maximum daily dose of 25 mg for 6 migraine days per month.

### ***Frova***

The recommended dose is a single 2.5 mg tablet taken orally with fluids. If the headache recurs after initial relief, a second tablet may be taken, providing there is an interval of at least 2 hours between doses. The total daily dose should not exceed 3 tablets (3 x 2.5 mg per day). There is no evidence that a second dose is effective in patients who do not respond to a first dose of the drug for the same headache. The safety of treating an average of more than 4 migraine attacks in a 30-day period has not been established.

The quantity limit is set at 12 of the 2.5 mg tablets. This limit allows for the treatment of 6 daily dose migraine days per month and also allows for the restriction of utilizing more than the maximum daily dose of 7.5 mg for 4 migraine days per month.

### ***Imitrex Injection***

The maximum single recommended adult dose for migraine and cluster headache is 6 mg injected subcutaneously. The maximum recommended dose that may be given in 24 hours is two 6-mg injections separated by at least 1 hour. Controlled clinical trials have failed to show that clear benefit is associated with the administration of a second 6-mg dose in patients who have failed to respond to a first injection.

The quantity limit is set at 12 STATdose systems, 12 STATEdose refills, or 2 packages of single dose vials (5 vials/package). The limit for the single dose vials is set at 5 mL, or 10 doses, per month because of manufacturer packaging and that pharmacies will not dispense partial packages.

### ***Imitrex Nasal Spray***

In controlled clinical trials, single doses of 5, 10, or 20 mg administered into 1 nostril were effective for the acute treatment of migraine in adults. A greater proportion of patients had headache response following a 20-mg dose than following a 5- or 10-mg dose. Individuals may vary in response to doses of the nasal spray. The choice of dose should therefore be made on an individual basis, weighing the possible benefit of the 20-mg dose with the potential for a greater risk of adverse events. A 10-mg dose may be achieved by the administration of a single 5-mg dose in each nostril. There is evidence that doses above 20 mg do not provide a greater effect than 20 mg. If the headache returns, the dose may be repeated once after 2 hours, not to exceed a total daily dose of 40 mg. The safety of treating an average of more than 4 headaches in a 30-day period has not been established.

The quantity limit is set at 12 units (2 packages) of the 5 or 20 mg nasal spray. This limit allows for the treatment of 6 daily dose migraine days per month and also requires the higher concentration product be dispensed if 20 mg doses are required.

### ***Imitrex Tablets***

In controlled clinical trials, single doses of 25, 50, or 100 mg tablets were effective for the acute treatment of migraine in adults. There is evidence that doses of 50 and 100 mg may provide a greater effect than 25 mg. There is also evidence that doses of 100 mg do not provide a greater effect than 50 mg. Individuals may vary in response to treatment. The choice of dose should therefore be made on an individual basis, weighing the possible benefit of a higher dose with the potential for a greater risk of adverse events. If the headache returns or the patient has a partial response to the initial dose, the dose may be repeated after 2 hours, not to exceed a total daily dose of 200 mg. If a headache returns following an initial treatment with the injection product, additional single tablets (up to 100 mg/day) may be given with an interval of at least 2 hours between tablet doses. The safety of treating an average of more than 4 headaches in a 30-day period has not been established.

The quantity limit is set at 12 of the 25, 50, or 100 mg tablets and is based on the treatment with 100 mg tablets. This limit allows for the treatment of 6 daily dose migraine days per month and also allows for the restriction of utilizing more than the maximum daily dose of 200 mg for 6 migraine days per month.

### ***Maxalt/Maxalt-MLT***

In controlled clinical trials, single doses of 5 and 10 mg of both formulations 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 treatment. The choice of dose should therefore be made on an individual basis, weighing the possible benefit of the 10 mg dose with the potential risk for increased adverse events. If redosing is necessary, doses should be separated by at least 2 hours; no more than 30 mg should be taken in any 24-hour period. The safety of treating, on average, more than 4 headaches in a 30-day period has not been established.

The quantity limit is set at 12 of the 5 or 10 mg tablets/orally disintegrating tablets. This limit allows for the treatment of 6 daily dose migraine days per month and also allows for the restriction of utilizing more than the maximum daily dose of 30 mg for 4 migraine days per month.

### ***Relpax***

In controlled clinical trials, single doses of 20 mg and 40 mg were effective for the acute treatment of migraine in adults. A greater proportion of patients had a response following a 40 mg dose than following a 20 mg dose. Individuals may vary in response to treatment. The choice of dose should therefore be made on an individual basis. An 80 mg dose, although also effective, was associated with an increased incidence of adverse events. Therefore, the maximum recommended single dose is 40 mg. If after the initial dose, headache improves but then returns, a repeat dose may be beneficial. If a second dose is required, it should be taken at least 2 hours after the initial dose. If the initial dose is ineffective, controlled clinical trials have not shown a benefit of a second dose to treat the same attack. The maximum daily dose should not exceed 80 mg. The safety of treating an average of more than 3 headaches in a 30-day period has not been established.

The quantity limit is set at 12 of the 20 or 40 mg tablets. This limit allows for the treatment of 6 daily dose migraine days per month and also allows for the restriction of utilizing more than the maximum daily dose of 80 mg for 6 migraine days per month.

### ***Treximet***

The fixed-dose combination contains doses of sumatriptan (85 mg) and naproxen sodium (500 mg) within the approved dosage ranges of the individual components (25 to 100 mg of sumatriptan and 220 to 825 mg of naproxen sodium). The product contains a dose of sumatriptan higher than the lowest effective dose. Individuals may vary in response to doses of sumatriptan. The choice of the dose of sumatriptan, and of the use of a fixed dose combination should therefore be made on an individual basis, weighing the possible benefit of a higher dose of sumatriptan with the potential for a greater risk of adverse events. Carefully consider the potential benefits and risks along with other treatment options when deciding to use. The recommended dose is 1 tablet. In controlled clinical trials, single doses of were effective for the acute treatment of migraine in adults. The efficacy of taking a second dose has not been established. Do not take more than 2 tablets in 24 hours. Dosing of tablets should be at least 2 hours apart. The safety of treating an average of more than 5 migraine headaches in a 30-day period has not been established.

The quantity limit is set at 9 fixed-dose combination tablets per month. Due to manufacturer labeling the product can not be repackaged and the product must be dispensed and stored in its original container. Therefore, packaging does not allow for dispensing in quantities other than nine. Additionally, the limit is set at one package because two packages would treat more than double the median number of migraine days per month that the quantity limits protocol has set at six.

### ***Zomig/Zomig-ZMT***

In controlled clinical trials, single doses of 1, 2.5 and 5 mg tablets were effective for the acute treatment of migraines in adults. 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, there was little added benefit from the larger dose but side effects are generally increased at 5 mg. Patients should, therefore, be started on 2.5 mg or lower. A dose lower than 2.5 mg can be achieved by manually breaking the scored 2.5 mg tablet in half. If the headache returns, 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. Zomig-ZMT 2.5 mg has been found in a controlled clinical trial to be effective for the acute treatment of migraines in adults. If the headache returns, 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.

The quantity limit is set at 12 of the 2.5 or 5 mg tablets (or orally disintegrating tablets). This limit allows for the treatment of 6 daily dose migraine days per month and also allows for the restriction of utilizing more than the maximum daily dose of 10 mg for 6 migraine days per month.

### ***Zomig Nasal Spray***

In controlled clinical trials, single doses of the 5 mg nasal spray were administered into one nostril and were effective for the treatment of acute migraines in adults. If the headache returns the dose may be repeated after 2 hours. The maximum daily dose should not exceed 10 mg in any 24-hour period. Individuals may vary in response to treatment. The pharmacokinetics of a 5 mg nasal spray dose is similar to the 5 mg oral formulations. Doses lower than 5 mg can only be achieved through the use of an oral formulation. The choice of dose, and route of administration should therefore be made on an individual basis. The effectiveness of a second dose has not been established in placebo-controlled trials. The safety of treating an average of more than four headaches in a 30-day period has not been established.

The quantity limit is set at 12 of the single dose nasal spray units. This limit allows for the treatment of 6 daily dose migraine days per month and also allows for the restriction of utilizing more than the maximum daily dose of 10 mg for 6 migraine days per month.

### **Ergotamines<sup>12-16</sup>**

#### ***Migergot rectal suppositories***

The recommended treatment is one rectal suppository at the start of attack and, if needed for full relief, a second suppository after 1 hour. The maximum dose should not exceed 2 suppositories per attack and the maximum weekly dosage is no more than 5 suppositories. Migergot suppositories should not be used for chronic daily administration.

The quantity limit is set at 20 rectal suppositories. This limit allows for the treatment of 6 daily dose migraine days per month and also allows for the restriction of utilizing more than the maximum weekly dose of 5 suppositories.

#### ***Cafergot, ergotamine tartrate/caffeine tablets***

For the best results, dosage should start at the first sign of an attack. Take 2 tablets at the start of attack; 1 additional tablet every 1/2 hour, if needed for full relief (maximum 6 tablets per attack, 10 per week). The maximum adult dosage for any one attack should not exceed 6 tablets. Total weekly dosage should not exceed 10 tablets. Ergotamine tartrate and caffeine tablets should not be used for chronic daily administration. In carefully selected patients, with due consideration of maximum dosage recommendations, administration of the drug at bedtime may be an appropriate short-term preventive measure.

The quantity limit is set at 40 tablets per month. This limit allows for the restriction of utilizing more than the maximum weekly dose of 10 tablets.

#### ***Ergomar sublingual tablets***

At the first sign of an attack or to relieve symptoms after onset of an attack, one 2 mg tablet is placed under the tongue. For best results, dosage should start at the first sign of an attack as early administration gives maximum effectiveness. Another tablet should be taken at half-hour intervals thereafter, if necessary, but dosage must not exceed three tablets in any 24-hour period. Total weekly dosage should not exceed five tablets (10 mg) in any one week and should not be used for chronic daily administration.

The quantity limit is set at 40 sublingual tablets per month. This limit allows for the restriction of utilizing more than the maximum weekly dose of 10 tablets.

**D.H.E. 45, dihydroergotamine mesylate injection USP**

The recommended dosing is a dose of 1 mL administered intravenously, intramuscularly, or subcutaneously. The dose can be repeated, as needed, at 1 hour intervals to a total dose of 3 mL for intramuscular or subcutaneous delivery or 2 mL for intravenous delivery in a 24 hour period. The total weekly dosage should not exceed 6 mL and should not be used for chronic daily administration.

The quantity limit is set at 20, 1 mL ampules per month. This limit allows for the treatment of 6 daily dose migraine days per month and also allows for the restriction of utilizing more than the maximum weekly dose of 6 mL.

**Migranal**

In clinical trials, Migranal Nasal Spray has been effective for the acute treatment of migraine headaches with or without aura. One spray (0.5 mg) should be administered in each nostril. Fifteen minutes later, an additional one spray (0.5 mg) should be administered in each nostril, for a total dosage of four sprays (2 mg). Studies have shown no additional benefit from acute doses greater than 2 mg for a single migraine administration. The safety of doses greater than 3 mg in a 24-hour period and 4 mg in a 7-day period has not been established and should not be used for chronic daily administration. This product is only formulated for intranasal use and should not be injected.

The quantity limit is set at 16 mL (2 packages of 8, 1 mL ampules) per month. This limit allows for the treatment of 6 daily dose migraine days per month and also allows for the restriction of utilizing more than the maximum of 2 ampules per 24 hours.

**Butorphanol tartrate nasal spray<sup>17</sup>**

Factors to be considered in determining the dose are age, body weight, physical status, underlying pathological condition, and the use of other drugs. Use in the elderly, in patients with hepatic or renal disease, or in labor requires extra caution. The following doses are for patients who do not have impaired hepatic or renal function and who are not on CNS active agents. The usual recommended dose for initial nasal administration is 1 mg (1 spray in one nostril). Adherence to this dose reduces the incidence of drowsiness and dizziness. If adequate pain relief is not achieved within 60 to 90 minutes, an additional 1 mg dose may be given. The initial dose sequence outlined above may be repeated in 3 to 4 hours as required after the second dose of the sequence. Depending on the severity of the pain, an initial dose of 2 mg (1 spray in each nostril) may be used in patients who will be able to remain recumbent in the event drowsiness or dizziness occurs. In such patients single additional 2 mg doses should not be given for 3 to 4 hours.

Note: Butorphanol tartrate has been associated with episodes of abuse and dependence.

The quantity limit is set at 3 canisters per month. On average, one bottle will deliver 14 to 15 doses if no repriming is necessary. The minimum amount of sprays per day to accommodate 18 wakeful hours is 12 (2 sprays every 3 hours). This limit allows for the treatment of 3 daily dose migraine days per month.

**Explanation of PA Criteria**

The purpose of the PA criteria is to allow approval for quantities above the maximum monthly quantity limits recommended in product labeling in specific situations. The criteria is based on current guidelines and practice parameters to assist in the treatment and prevention of migraine headaches and requires a diagnosis of migraine headache to fulfill the approved indications provided in the product labeling.

Preventative treatment is recommended in patients that develop medication-overuse headaches<sup>18-20</sup> and should be strongly considered if use of acute medication escalates or the patient has five or more headaches per month.<sup>23</sup> Preauthorization requests for quantities greater than the monthly limit may be approved if the patient is currently utilizing prophylactic medication, if the prescriber determines that prophylactic medications are inappropriate, or if the patient refuses prophylactic medication when acute therapy is necessary. Requests for quantities greater than the limit will require medication-overuse headaches evaluations prior to approval.

The combination of multiple triptan medications or triptans and ergotamine products are contraindicated.

## References

1. Amerge<sup>®</sup> (naratriptan hydrochloride) [package insert]. Research Triangle Park, NC: GlaxoSmithKline, October 2007.
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3. Frova<sup>®</sup> (frovatriptan succinate) [package insert]. Chadds Ford, PA: Endo Pharmaceuticals Inc., April 2007.
4. Imitrex<sup>®</sup> (sumatriptan) Nasal Spray [package insert]. Research Triangle Park, NC: GlaxoSmithKline, October 2007.
5. Imitrex<sup>®</sup> (sumatriptan succinate) tablets [package insert]. Research Triangle Park, NC: GlaxoSmithKline, October 2007.
6. Maxalt/Maxalt-MLT<sup>®</sup> (rizatriptan benzoate) [package insert]. Whitehouse Station, NJ: Merck & Co., Inc., February 2008.
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## Billing/Coding

CODES	NUMBER	DESCRIPTION
GPI	674060*****	Selective serotonin agonists 5-HT (1)
	6799100210****	Ergotamine w/caffeine
	6799200260****	Sumatriptan/naproxen sodium
	67000020*****	Ergotamine tartrate
	67000030*****	Dihydroergotamine mesylate
	65200020102050	Butorphanol tartrate nasal solution 10 mg/mL
HCPCS	J1110	Injection, Dihydroergotamine mesylate, per 1 mg

Type of Service	Prescription Drug	
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Place of Service	Outpatient	
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## Update Information

Date	Action	Reason
07/01/08	Replace PA criteria	New PA criteria

## Preauthorization Criteria History

06/26/08	Reviewed by QMC
07/01/08	Preauthorization criteria original effective date
June 2009	Next Review