



## Triptans Step Therapy/Quantity Limit Criteria

Program may be implemented with the following options

- 1) step therapy
- 2) quantity limits or
- 3) step therapy with quantity limits

For Blue Cross and Blue Shield of Illinois Option 1 (step therapy only) will apply.

Brand	Generic	Dosage Form
Amerge <sup>®</sup>	naratriptan	tablets
Axert <sup>®</sup>	almotriptan	tablets
Frova <sup>®</sup>	frovatriptan	tablets
Imitrex <sup>®</sup>	sumatriptan	injection*, nasal spray, tablets*
Maxalt <sup>®</sup>	rizatriptan	tablets
Maxalt-MLT <sup>®</sup>	rizatriptan	tablets
Relpax <sup>®</sup>	eletriptan	tablets
Treximet <sup>™</sup>	sumatriptan and naproxen	tablets
Zomig <sup>®</sup>	zolmitriptan	tablets, nasal spray
Zomig-ZMT <sup>®</sup>	zolmitriptan	tablets

\* generic available and included as target agent in quantity limit edit

### FDA APPROVED INDICATIONS<sup>1-7</sup>

The following information is taken from individual drug prescribing information and is provided here as background information only. Not all FDA-approved indications may be considered medically necessary. All criteria are found in the section "Prior Authorization Criteria for Approval."

**Amerge<sup>®</sup> Tablets<sup>1</sup>, Axert<sup>®</sup> Tablets<sup>2</sup>, Frova<sup>®</sup> Tablets<sup>3</sup>, Imitrex<sup>®</sup> injection<sup>4</sup>, Imitrex Nasal Spray<sup>5</sup>, Imitrex Tablets<sup>6</sup>, Maxalt<sup>®</sup> Tablets<sup>7</sup>, Maxalt-MLT<sup>®</sup> Tablets<sup>7</sup>, Relpax<sup>®</sup> Tablets<sup>8</sup>, Treximet<sup>™</sup> Tablets<sup>9</sup>, Zomig<sup>®</sup> Tablets<sup>10</sup>, Zomig-ZMT<sup>®</sup> Tablets<sup>10</sup>, and Zomig<sup>®</sup> Nasal Spray<sup>11</sup>**

Amerge (naratriptan), Axert (almotriptan), Frova (frovatriptan), Imitrex (sumatriptan), Maxalt (rizatriptan), Maxalt-MLT (rizatriptan orally disintegrating), Relpax (eletriptan), Treximet (sumatriptan/naproxen), Zomig (zolmitriptan), and Zomig-ZMT (zolmitriptan orally disintegrating) tablets, and Imitrex (sumatriptan) and Zomig (zolmitriptan) nasal spray are all indicated for the acute treatment of migraine attacks 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 of all of these products have not been established for cluster headache, which is present in an older, predominantly male population.

### Imitrex® Injection<sup>4</sup>

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

### RECOMMENDED QUANTITY LIMITS <sup>1-11</sup>

Agent	Strength/ Formulation	How Supplied	Maximum 24- Hour Dose <sup>a</sup>	Accumulation Value per Month Limit	
Amerge®	1 mg tablets	9-tablet blister packs	5 mg	18 tablets	
	2.5 mg tablets	9-tablet blister packs		18 tablets	
Axert®	6.25 mg tablets	6-tablet blister packs	25 mg	12 tablets	
	12.5 mg tablets	6-tablet blister packs 12-tablet blister packs		12 tablets	
Frova®	2.5 mg tablets	9 tablets/ package	7.5 mg	18 tablets	
Imitrex®/ sumatriptan	4mg STATdose® system	2 single doses/pkg	12 mg	12 doses (6 packages)	
	4mg STATdose® refills	2 single doses/pkg		12 doses (6 packages)	
	4 mg/0.5 mL vial	single dose/vial		12 doses (12 vials or 6 mL)	
	6mg STATdose® system	2 single doses/pkg		12 doses (6 packages)	
	6mg STATdose® refills	2 single doses/pkg		12 doses (6 packages)	
	6mg/0.5ml single dose vial <sup>b</sup>	5 x 0.5ml/package		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 <sup>b</sup>	9 tablets/package	200 mg	18 tablets
		50mg tablets <sup>b</sup>	9 tablets/package		18 tablets
100mg tablets <sup>b</sup>		9 tablets/package	18 tablets		
Maxalt®	5 mg tablets	6-, 9- and 12-tablet blister packs Bottles of 30, 60, 90 and 100 tablets	30 mg	24 tablets	
	10 mg tablets	3, 6, 9 and 12-tablet blister packs		24 tablets	
	5 mg MLT tablets	3, 6, 9 and 12-tablet blister packs		24 tablets	
	10 mg MLT tablets	3 and 9-tablet blister packs		24 tablets	
Relpax®	20 mg tablets	6-tablet blister cards	80 mg	12 tablets	
	40 mg tablets	Pkgs of 1 or 2, 6-tablet blister cards		12 tablets	
Treximet™	85/500 mg tablets	9 tablets/package	2 tablets	18 tablets	
Zomig®	2.5 mg tablets	6-tablet blister packs	10 mg	12 tablets	
	5 mg tablets	3-tablet blister packs Bottles of 30,60,90, and 100 tablets		12 tablets	
	2.5 mg ZMT tablets	6-tablet blister packs		12 tablets	
	5 mg ZMT tablets	3-tablet blister packs		12 tablets	
	5 mg/100 µL nasal spray	6-single use nasal spray units/package		12 nasal spray units	

a Recommended maximum 24-hour dose may be modified in hepatic or renal insufficiency or in patients concurrently receiving interacting medications

b available as a generic

### RATIONALE FOR STEP THERAPY AND QUANTITY LIMITS

#### Step Therapy

The intent of the step therapy criteria for the triptan agents is to accommodate for use of brand triptans when the more cost-effective generic sumatriptan cannot be used due to allergy, intolerance, contraindication, or treatment failure or the brand agent is a recommended first-choice agent for the diagnosis. The step therapy edit will be applied to patients initiating therapy with a triptan agent.

Patients who are currently being treated with a brand agent will be allowed to continue therapy with the brand if found in the patient's claims history or medication history.

Guidelines for the treatment of acute migraine headache indicate that treatment with any triptan is a reasonable first-choice agent for moderate to severe migraine headache in adults. [see formulary chapter 10.4A: Triptans: Guidelines-US Headache Consortium Recommendations (2000), American Association of Family Practitioners/American College of Physicians (2002)<sup>12</sup>]. Additional guidelines including The Institute for Clinical Systems Improvement (ICSI 2007) Health Care Guideline: Diagnosis and Treatment of Headache<sup>13</sup> and the British Association for the Study of Headache (BASH 2007): Guidelines for All Healthcare Professionals in the Diagnosis and Management of Migraine, Tension-type, Cluster and Medication-overuse Headache<sup>14</sup> also recommend the use of any triptan as a first-line agent for treatment of migraine headache.

Clinical trials indicate that triptan agents may differ in comparable efficacy. [see formulary chapter 10.4A: Triptans: Uniqueness: Efficacy of other triptans compared to sumatriptan 100 mg<sup>12</sup>] However, there are unpredictable individual variations in response to the triptan agents.<sup>14</sup> Approximately 30 percent of patients fail to respond to any particular triptan, and failure may be attributable to various factors including low and inconsistent absorption, administration of the agent too early or too late in the attack, inadequate dose, or individual biological variability.<sup>15</sup> Patients responding poorly to one triptan may benefit from another in subsequent migraine attacks.<sup>14,16</sup> The edit will allow patients who are already stable on an effective brand agent to continue therapy with that agent.

Sumatriptan injection is the only triptan approved by the Food and Drug Administration (FDA) for the treatment of acute cluster headache and is the only proven highly effective acute treatment.<sup>17</sup> Sumatriptan 20 mg nasal spray and zolmitriptan 5 mg and 10 mg nasal spray have demonstrated effectiveness in placebo-controlled trials although response rates were lower than injectable sumatriptan.<sup>18,19</sup> Imitrex Nasal Spray and Zomig Nasal Spray may be considered as alternate treatment for acute cluster headache attacks when sumatriptan injection is not considered an appropriate choice for an individual patient.

The European Federation of Neurological Societies (EFNS) guidelines on the treatment of cluster headache and other trigeminal-autonomic cephalgias (2006) recommend inhalation of 100% oxygen as the first option for treatment of acute attacks of cluster headache or sumatriptan 6 mg subcutaneously.<sup>20</sup> Sumatriptan 20 mg nasal spray or zolmitriptan 5 mg nasal spray are considered alternatives, with the disadvantage of slower onset of action and the advantage of treating more attacks in 24 hours than sumatriptan injection.<sup>20</sup> Oral zolmitriptan 5 mg and 10 mg have shown efficacy in some patients but high doses result in more side effects and limit use.<sup>20</sup> The step therapy edit is designed to allow payment for brand triptan agents when generic sumatriptan (oral tablets or injection) have been previously prescribed and are electronically identified. The edit will also allow payment of the identical brand agent if found in the claims history within a 90 day look back parameter. The manual prior authorization (PA) process allows brand use when the patient has an allergy, contraindication, or intolerance to generic sumatriptan or if previous use of generic sumatriptan is not apparent in claims history or if the patient is being successfully treated with the requested brand agent.

### **Quantity Limits**

The intent of the recommended quantity limit is to provide automatic approval for patients with three or fewer migraine or cluster headaches per month (two headache days per episode) and to require individual evaluation through the PA procedure for patients who have more headaches per month and exceed this limit. Additionally, the intent of the quantity limit and PA criteria together is to ensure that patients and physicians address the current guidelines for the prevention and treatment of migraine and/or cluster headache.

Evidence-based guidelines and published practice parameters from the American Academy of Neurology (AAN) for the pharmacologic management of migraine headaches suggest that acute therapy should be limited to no more than two headache days per week to guard against medication-

overuse headache.<sup>21</sup> AAN guidelines also recommend preventive treatment for those patients whose migraine has a substantial negative impact on their lives and acute medications have not resolved migraine attacks, or where the frequency of attacks has increased the use of acute medications to a level that would increase the potential for medication overuse headaches.<sup>21,22</sup> Medication overuse headache is now included in the International Classification of Headache Disorders.<sup>23,24</sup> According to this classification, medication overuse headache can be diagnosed when headaches occur on 15 or more days per month, the pain is characterized as bilateral, dull, and of light to moderate intensity, drug intake includes ergots, triptans and opioids for ten or more days per month or analgesics are used for 15 or more days per month for at least three months, and the headache disappears after withdrawal.<sup>23,24</sup>

In general, if (migraine) headaches occur one to two days per month, there is usually no need for preventive therapy; if headaches occur three to four days per month, preventive therapy should be considered; if the patient has five or more attacks per month, preventive therapy should be seriously considered.<sup>25</sup> Patients and their health care providers should together decide how to treat acute attacks and whether to use preventive medications for migraine.<sup>10</sup>

Based on published data from a 1989 survey,<sup>26</sup> the median frequency of migraine attacks is 1.5 per month, and the median duration of an attack is 24 hours; at least 10% of patients have weekly attacks, and 20% have attacks lasting two to three days.<sup>26</sup> Additional surveys from the mid to late 1990's have confirmed these data.<sup>27-30</sup> Survey results continue to report a median attack duration of 24 hours; 54% to 63% of patients report monthly attacks and 13% to 25% report weekly attacks.<sup>27-30</sup>

Criteria for diagnosing cluster headache have been defined by the International Headache Society.<sup>23</sup> To fulfill criteria for diagnosis, patients must have had at least 5 attacks occurring from one every other day to eight per day; and attributable to no other disorder. In addition, headaches must cause severe or very severe unilateral orbital, supraorbital, or temporal pain lasting 15 to 180 minutes if untreated, and be accompanied by one or more of the following: ipsilateral conjunctival injection or lacrimation, ipsilateral nasal congestion or rhinorrhea, ipsilateral eyelid edema, ipsilateral forehead and facial sweating, ipsilateral miosis or ptosis, or a sense of restlessness or agitation. The name cluster refers to active periods lasting typically a few weeks when the subject experiences many attacks, most often at night, generally followed by inactive months. During a cluster period acute attacks must be aborted or subdued and prophylaxis should be initiated to suppress the recurrent headaches expected, to reduce attack frequency. Subcutaneous sumatriptan is the treatment of choice for acute therapy; the use of other triptans by other routes of administration is less well studied. Prophylactic therapy may include verapamil, corticosteroids, lithium, topiramate, or valproic acid. Reported studies show decreased attack frequency with these agents, but optimal efficacy may not be evident until after several days to a week of therapy, necessitating availability of abortive therapy.<sup>23,31-33</sup>

The quantity limit is designed to accommodate two times the median frequency of migraine attacks (three headaches) and two times the median of attack duration (2 days). Therefore, the limit is set at six days of headache per month. A prior authorization evaluation is available for patients requesting to exceed the quantity limit.

## **ELECTRONIC EDITS**

***Information from below will apply only if that program is implemented. If there are both step therapy and quantity limit programs implemented, requirements from both must be met for a claim to process.***

### ***Step Therapy***

The overall process for step therapy requires that another drug or drugs be tried for a specific quantity of drug in the previous time period before the claim drug. If the patient has met any of the requirements outlined below, the requested step therapy medication will be paid under the patient's current prescription benefit. If the patient does not meet the step therapy criteria, then the system will

reject with the message indicating that prior authorization is necessary or that higher co-pay(s) will be applicable. The PA criteria for approval would then be applied to requests submitted by the patient's practitioner for evaluation.

The step therapy edit for the triptan agents requires that generic sumatriptan be tried before a brand agent. Claims for a brand agent will be paid under the patient's current prescription benefit if a claim for generic sumatriptan is found in the patient's claims history within the previous 90 days or if the requested brand agent is identified in the previous 90 days. The electronic edit is designed to identify claims with a days supply that begins or ends within the 90 day look-back parameter. If the criteria has been implemented with the quantity limit edit the step therapy quantity limit requirements outlined in the electronic quantity limit edit must also be met for the claim to pay automatically.

**Table 1: Summary of Electronic Edit for Triptan Step Therapy**

Targeted Agent(s)	Amerge, Axert, Frova, Imitrex, Maxalt, Relpax, Treximet, Zomig
Is auto-grandfathering implemented? (with look-back time frame)	Yes (90 days <sup>a</sup> )
Prerequisite Agent(s)	sumatriptan (multisource code: Y)
Number of prerequisites required	1
Prerequisite look-back time frame	90 days <sup>a</sup>
Age-related edit?	NA
Additional comments	

a - The system searches for a claim with a days supply that begins or ends in the past 90 days. For claims with a 30 day supply the system would be able to identify a claim processed for payment between 1 and 120 days prior to the new claim. For claims that are dispensed as an extended days supply (90 days), the system would identify a claim processed between 1 and 180 days.

**Table 2: Details of Electronic Edit for Triptan Step Therapy**

Targeted Agents	GPIs	Prior Agents	GPIs	Look-back Time frames
<b>Brand Triptans</b> Amerge Axert Frova Imitrex Maxalt Treximet Relpax Zomig	674060***** and multisource code M, N, or O	<b>Prerequisite</b> Generic sumatriptan	67406070***** and multisource code Y	<b>Prerequisite look-back time frame:</b>  90 days <sup>a</sup>
		<b>For Auto-grandfathering of identical brand triptan:</b>	674060***** and multisource code M, N, or O, set up at drug or GPI 10 level	<b>Auto-grandfathering look-back time frame:</b>  90 days <sup>a</sup>

a - The system searches for a claim with a days supply that begins or ends in the past 90 days. For claims with a 30 day supply the system would be able to identify a claim processed for payment between 1 and 120 days prior to the new claim. For claims that are dispensed as an extended days supply (90 days), the system would identify a claim processed between 1 and 180 days.

If the patient does not meet the step therapy criteria, then the system will reject with the message indicating that prior authorization is necessary. The *Prior Authorization (PA) Criteria for Approval* would then be applied to requests submitted by the patient's practitioner for evaluation.

**Quantity Limit**

The overall process for the quantity limit edit requires that the quantity prescribed does not exceed a set quantity per time period for the requested drug. If this requirement is not met, the system will reject the payment and a message indicating that PA is necessary will be transmitted to the pharmacy. The PA criteria for approval would then be applied to requests submitted by the patient's practitioner for evaluation.

Quantity limits for the triptan agents have been calculated to accommodate six headache days per month. Product packaging has been taken into account to avoid dispensing of partial packages. Quantities are defined in the Recommended Quantity Limits table. If the quantity requested per month does not exceed the set monthly quantity limit the claim will pay automatically. Quantities exceeding the set limit will require evaluation through the manual PA process. (If the criteria has been implemented with the step therapy edit the step therapy requirements outlined in the electronic step therapy edit must also be met for the claim to pay automatically).

## **PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

The intent of the *Prior Authorization (PA) Criteria for Approval* is to provide a manual review process for claims that do not meet the electronic edit criteria and are not automatically paid. The criteria for approval through the PA process are identical to those set up in the electronic edit.

### ***Step Therapy***

The intent of the *PA Criteria for Approval* for step therapy is to allow for approval of brand triptan agents when the patient's medication history indicates prior sumatriptan use not previously identified by the electronic claims history edit. The PA criteria also allows for use of brand agents if the patient has allergies, intolerance, or contraindication to the use of sumatriptan or if the patient has been successfully treated with the requested agent.

### ***Quantity Limit***

The intent of the PA criteria for triptan quantity limit is to allow for review of requests through the Clinical Review process for quantities exceeding the determined limit. Requests for larger quantities may be approved when the agent is prescribed for treatment of cluster headache or if the patient is on prophylactic therapy unless unable to be treated with prophylactic therapy and the patient is not being concomitantly treated with another triptan or ergotamine product. Generic sumatriptan is included as a target agent in the quantity limit edit.

## **Step Therapy/Quantity Limit PA Criteria for Approval**

### ***Triptan Step Therapy***

#### **Initial and Renewal Evaluation**

1. Does the patient's medication history indicate previous use of the requested brand agent?  
If yes, approve indefinitely. If no, continue to 2.
2. Does the patient's medication history indicate previous use of sumatriptan?  
If yes, approve for requested agent indefinitely. If no, continue to 3.
3. Does the patient have an allergy, contraindication, or intolerance to sumatriptan?  
If yes, approve for requested agent indefinitely. If no, deny.

### ***Triptan Quantity Limit***

#### **Initial and Renewal Evaluation**

1. Is the quantity requested within the set limit?  
If yes, review is not applicable. Claim will adjudicate. If no, continue to 2.
2. Has the patient been diagnosed with:
  - a. Migraine headache
  - b. Cluster headache
  - c. OtherIf a, continue to 4. If b, continue to 3. If c, deny.

3. Has the patient been prescribed sumatriptan injection, Imitrex Nasal Spray, or Zomig Nasal Spray for the treatment of cluster headache?  
If yes, approve the requested agent for the quantity requested for 12 months. If no, deny.
4. Is the patient currently prescribed prophylactic migraine medication?  
If yes, continue to 6. If no, continue to 5.
5. Has the physician determined that the patient has an allergy, contraindication, intolerance, or treatment failure to prophylactic migraine therapy or does the patient refuse prophylactic therapy?  
If yes, continue to 6. If no, deny.
6. Has the physician evaluated the patient for medication overuse headache?  
If yes, continue to 7. If no, deny.
7. Is the patient taking this medication in combination with another triptan (e.g., Amerge, Axert, Imitrex, Frova, Maxalt, Maxalt-MLT, Relpax, Treximet, Zomig, Zomig-ZMT) or an ergotamine (e.g., Migranal<sup>®</sup>, DHE<sup>®</sup>, Cafergot<sup>®</sup>)? (Patient should not take together due to possibility of increased blood pressure effect.)  
If yes, deny. If no, approve the quantity requested (may include all dosage forms) for 12 months.

***Triptan Step Therapy with Quantity Limit***  
**Initial and Renewal Evaluation**

1. Does the patient's medication history indicate previous use of the requested agent?  
If yes, continue to 4. If no, continue to 2.
2. Does the patient's medication history indicate previous use of sumatriptan?  
If yes, continue to 4. If no, continue to 3.
3. Does the patient have an allergy, contraindication, or intolerance to sumatriptan?  
If yes, continue to 4. If no, deny.
4. Is the quantity requested within the set limit?  
If yes, approve indefinitely. If no, continue to 5.
5. Has the patient been diagnosed with:
  - a. Migraine headache
  - b. Cluster headache
  - c. Other
 If a, continue to 7. If b, continue to 6. If c, deny.
6. Has the patient been prescribed sumatriptan injection, Imitrex Nasal Spray, or Zomig Nasal Spray for the treatment of cluster headache?  
If yes, approve the requested agent for the quantity requested for 12 months. If no, deny.
7. Is the patient currently prescribed prophylactic migraine medication?  
If yes, continue to 9. If no, continue to 8.
8. Has the physician determined that the patient has an allergy, contraindication, intolerance, or treatment failure to prophylactic migraine therapy or does the patient refuse prophylactic therapy?  
If yes, continue to 9. If no, deny.
9. Has the physician evaluated the patient for medication overuse headache?  
If yes, continue to 10. If no, deny.

10. Is the patient taking this medication in combination with another triptan (e.g., Amerge, Axert, Imitrex, Frova, Maxalt, Maxalt-MLT, Relpax, Treximet, Zomig, Zomig-ZMT) or an ergotamine (e.g., Migranal<sup>®</sup>, DHE<sup>®</sup>, Cafergot<sup>®</sup>)? (Patient should not take together due to possibility of increased blood pressure effect.)  
If yes, deny. If no, approve the quantity requested (may include all dosage forms) for 12 months.

## SUMMARY

Step therapy electronic edits are designed to allow for use of brand triptan agents when claims history indicates prior generic triptan use or if the patient has been previously treated with the requested agent. The intent of the quantity limits for triptan agents is to encourage appropriate prescribing and to decrease the risk of developing medication overuse headache. Through the PA process brand triptan agents may be approved if patients are not able to take generic agents due to allergy, contraindication, or intolerance. Quantities exceeding the set limit may be appropriate when used for cluster headache or if the patient is unable to use prophylactic medication for frequent migraine headaches that are not caused by medication overuse.

## REFERENCES

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11. Zomig<sup>®</sup> Nasal Spray prescribing information. AstraZeneca Pharmaceuticals LP. October 2008.
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**Quantity Limits Document History**

Revised Prime Standard approved UMC 08/2004  
 Annual Review with changes approved by External UMC 11/2005  
 Administrative revision addition of Imitrex 4mg STATdose 04/2006  
 Annual Review with changes approved by External UM Committee 08/2006  
 Midyear Review with quantity limit changes for Maxalt/Maxalt MLT approved by External UM Committee 08/2007  
 Annual Review with changes approved by External UM Committee 11/12007

**Step Therapy/Quantity Limits Document History**

Original Prime Standard ST/QL combined criteria approved by P&T UM Committee 11/2008  
 Administrative addition of sumatriptan 4 mg/0.5 mL 1-mL multi-dose vial 05/2009  
 Annual review pending approval by P&T UM Committee 08/2009  
 Initial Client Review, Prime Standard Criteria (ST only) approved by HCSC Corporate Clinical Committee 08/2009