



Medication Policy Manual

Policy No: dru055

Topic: Imitrex[®], sumatriptan

Date of Origin: April 22, 2002

Revised Date: October 28, 2009

Next Review Date: November 2010

Effective Date: December 1, 2009

IMPORTANT REMINDER

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Sumatriptan (Imitrex[®]), is a rescue treatment for immediate pain relief of an acute migraine headache attack.

Policy/Criteria

I. Sumatriptan in quantities up to 12 tablets, 6 nasal spray canisters or 6 injections per month may be considered medically necessary and may be covered without authorization.

II. Sumatriptan in quantities of 13 to 24 tablets per month may be considered medically necessary when either criteria A or B are met:

A. Diagnosis of **cluster headache**.

OR

B. Diagnosis of **migraine headache** and the following criteria below are met.

1. Prophylaxis with medications from three of the different therapy classes listed in Appendix 1 has been ineffective, not tolerated, or contraindicated.

AND

2. There is documentation of migraine prophylaxis within the last four months.

III. Sumatriptan in quantities of 7 to 12 injections or nasal spray canisters per month, may be considered medically necessary when either criterion A or B are met:

A. Diagnosis of **cluster headaches**.

OR

B. Diagnosis of **migraine headache** and the following criteria 1, 2 and 3 below are met.

1. Prophylaxis with medications from three of the different therapy classes listed in Appendix 1 has been ineffective, not tolerated, or contraindicated.

AND

2. There is documentation of migraine prophylaxis within the last four months.

AND

3. Headaches are associated with nausea/vomiting.

IV. Administration, Quantity Limitations and Authorization Period

A. Regence considers sumatriptan to be a self-administered medication.

- B. Quantities exceeding 24 tablets or 12 injections or 12 nasal sprays per month (in any combination of triptan products) are considered not medically necessary.
- C. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

Position Statement

Summary

- For the treatment of migraine headache, the preferred/formulary triptan medications sumatriptan (Imitrex[®]), rizatriptan (Maxalt[®]), and eletriptan (Relpax[®]), are the best value and have the best evidence of effectiveness.
- There is reliable evidence that almotriptan (Axert[®]) and zolmitriptan (Zomig[®]) stops migraines, but they have no proven additional benefit over preferred/formulary options to justify the higher cost.
- Sumatriptan is used for the acute treatment of migraine attacks with or without aura and sumatriptan injection is used for the acute treatment of cluster headache episodes.
- All triptans are effective and relatively safe for the acute treatment of moderate to severe migraine headaches. ^[1-8, 22, 29, 33-34]
- There is reliable evidence that preventive medications help gain control of migraine headaches by reducing how often they occur and the severity.

Clinical Efficacy

- The evidence for the preferred nasal and oral triptans is reliable for the acute treatment of migraine attacks. ^[1-7] There is not reliable evidence for the treatment of other types of headaches. ^[1-8]
- Sumatriptan (Imitrex) injection has the best evidence for the treatment of cluster headaches. ^[1]
- Among the available triptans, there is no reliable evidence that almotriptan (Axert), frovatriptan (Frova) or naratriptan (Amerge) offer additional clinical benefits: ^[17-21, 26-28]
 - * in headache relief at two hours
 - * in headache recurrence rates

- There is some evidence that eletriptan has a lower migraine recurrence rate at two hours than oral sumatriptan. ^[31-32]
- There is reliable evidence that almotriptan, sumatriptan, rizatriptan, eletriptan, and zolmitriptan abort migraine headaches and treat the associated symptoms. Approximately three to five patients need to be treated for one to have a response.
- The clinical value of naratriptan, frovatriptan and sumatriptan/naproxen is uncertain because there is not reliable evidence to determine how well they treat migraines.
- Because migraines are often accompanied by nausea, products with multiple dosage forms such as oral disintegrating tablets, nasal sprays and injectable dosage forms provide additional clinical value for patients who cannot tolerate swallowing tablets.
- There is insufficient evidence that demonstrates that one triptan is more efficacious than another in the treatment of migraine headache.
- A triptan taken at the first sign of a migraine yields the best response (pain free, or significant decrease in pain).
- There is no reliable evidence that the addition of naproxen to sumatriptan is effective.

Safety

PREVENTIVE (PROPHYLACTIC) THERAPY

- Patients who suffer very severe or frequent migraine attacks may benefit from preventative therapy. ^[10]
- Current medical literature suggests that preventative therapy should be considered in patients experiencing greater than two migraine attacks per month. ^[10, 11]
- Preventative medication can help most people decrease the number of migraine headaches by half. Approximately one in ten patients become migraine free with preventative medication. ^[11, 14]
- Consultation with a specialist experienced in the evaluation and treatment of refractory headache patients may be beneficial when three or more successive preventative drugs have not been effective. ^[14]
- The American Academy of Neurology states that preventative medication may be indicated when a patient is experiencing one or more migraines per week. Severe may be defined as headache causing work loss.
- Frequent use of quick relief medication may cause medication overuse headache.

- Many experts limit quick relief therapy to two headaches per week on a regular basis. Patients with medication overuse headache should use preventive medication. ^[15]
- The American Academy of Neurology has suggests the best evidence for preventative drug efficacy is for amitriptyline, propranolol, timolol, and divalproex sodium. Evidence of efficacy also exists for other beta-blockers, tricyclics, and verapamil. ^[15]
- Triptans do not prevent migraines. ^[1-8, 22, 29, 33-34]

MAXIMUM QUANTITIES

- Most people who have migraine headaches need fewer than 12 tablets per month.
- Approximately 85% of patients with migraine headaches suffer fewer than three to four attacks per month. ^[9] The median frequency of migraine attacks among migraine sufferers is 1.5 per month. ^[11]
- Frequent use of quick relief medications can lead to medication overuse headache and eventually chronic daily headache (medication overuse headache is defined as headache frequency of more than 15 days per month after the frequent intake of quick relief medications for a minimum of three months). ^[10]
- Frequent use of triptans may lead to medication overuse headache. ^[12, 13]
- Medication overuse headache is the most common factor in patients referred to tertiary headache clinics. ^[14]
- The safety of treating more than four headaches with almotriptan, naratriptan, sumatriptan, frovatriptan, rizatriptan, or zolmitriptan (nasal spray) in a 30-day period has not been established. ^[1-7, 34-35]
- The safety of treating more than three headaches with zolmitriptan tablets or eletriptan in a 30-day period has not been established. ^[4, 33]
- The safety of treating an average of more than 5 migraine headaches in a 30-day period has not been established for sumatriptan/naproxen. ^[38]
- The manufacturer's recommended dose for sumatriptan/naproxen is one tablet. The efficacy of taking a second dose has not been established. ^[38]
- The prescribing information states not to take more than two sumatriptan/naproxen tablets in 24 hours. ^[38]

Appendix 1: Migraine Prophylaxis Drug Therapy Classes

The following are examples of medication classes used for migraine prophylaxis:

-	Anticonvulsants (divalproex sodium).
-	Beta Blockers (propranolol, atenolol, metoprolol).
-	Calcium Channel Blockers (verapamil).
-	Tricyclic Antidepressants (amitriptyline).

Appendix 2: Product Availability

Brand Name	Generic Name	Dosage Form	Doses per Headache	Doses per Month (4 headaches) [b]	Strengths Available	Doses per package
FORMULARY/PREFERRED TRIPTANS						
sumatriptan	sumatriptan	Tablet	1 to 2 ^[a]	4 to 8	25mg, 50mg, 100mg	9 tablets
sumatriptan	sumatriptan	Nasal Spray	1 to 2 ^[a]	4 to 8	5mg, 20mg	6 sprays
sumatriptan	sumatriptan	Injection	1	4	6mg/0.5ml	2 syringes
Maxalt [®] , Maxalt MLT [®]	rizatriptan	Tablet	1 to 3 ^[a]	4 to 12	5mg, 10mg	6 tablets
Relpax [®]	eletriptan	Tablet	1 to 2 ^[a]	4 to 8	20mg, 40mg	6 tablets 12 tablets

Brand Name	Generic Name	Dosage Form	Doses per Headache	Doses per Month (4 headaches) ^[b]	Strengths Available	Doses per package
NON-FORMULARY/NON-PREFERRED TRIPTANS						
Amerge [®]	naratriptan	Tablet	1 to 2 ^[a]	4 to 8	1mg, 2.5mg	9 tablets
Axert [®]	almotriptan	Tablet	1	4	6.25mg, 12.5mg	6 tablets 12 tablets
Frova [®]	frovatriptan	Tablet	1 to 3 ^[a]	4 to 12	2.5mg	9 tablets
Imitrex [®]	sumatriptan	Tablet	1 to 2 ^[a]	4 to 8	25mg, 50mg, 100mg	9 tablets
Imitrex [®]	sumatriptan	Nasal Spray	1 to 2 ^[a]	4 to 8	5mg, 20mg	6 sprays
Imitrex [®]	sumatriptan	Injection	1	4	6mg/0.5ml	2 syringes
Sumavel [™] DosePro [™]	sumatriptan	Injection	1	4	6mg/0.5ml	6 syringes
Treximet [®]	sumatriptan/ naproxen	Tablet	1 to 2 ^[a]	5 to 10	85mg/500mg	9 tablets
Zomig [®]	zolmitriptan	Nasal Spray	1 to 2	4 to 8	5mg	6 sprays
Zomig [®] , Zomig ZMT [®]	zolmitriptan	Tablet	1	4	2.5mg, 5mg	6 tablets 3 tablets
a. Dose may be repeated if first dose was not completely effective.						
b. Headache recurs in less than 46% of patients within 24 hours. ^[16]						

Appendix 3: Cluster Headache Diagnostic Criteria

1. Severe unilateral orbital, supraorbital, and/or temporal pain lasting 15-180 minutes untreated.

AND

2. Headache is associated with at least one of the following signs on the pain side:

a. Conjunctival injection

b. Lacrimation

c. Nasal congestion

d. Rhinorrhea

e. Forehead/facial sweating

f. Miosis

g. Ptosis

h. Eyelid edema

AND

3. Current frequency of attack is at least 1 every other day.

AND

4. At least five attacks have occurred fulfilling the criteria listed above.

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Cross References
Amerge [®] , naratriptan dru052
Axert [®] , almotriptan dru053
Frova [®] , frovatriptan dru078
Maxalt [®] /Maxalt MLT [®] , rizatriptan dru056
Relpax [®] , eletriptan dru092
Sumavel [™] DosePro [™] , sumatriptan injection dru191
Treximet [®] , sumatriptan/naproxen dru165
Zomig [®] /Zomig ZMT [®] , zolmitriptan dru057

Codes	Number	Description
N/A		