

Policies Repository



Policy Title Migraine Agents

Policy Number FS.CLIN.34

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This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Migraine agents** (eg, 5-hydroxytryptamine₁ receptor agonists) are used for the treatment of migraine headaches. These agents are subject to quantity limits and require prior authorization for quantities above the limits. The current quantity limits allow for the treatment of four to six acute migraine headaches per month and were developed based on US Food and Drug Administration (FDA) recommendations.

The use of triptans, dihydroergotamine nasal spray, and butorphanol nasal spray, when prescribed for quantities that exceed the quantity limits, requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Migraine headaches are believed to result from the dilatation of blood vessels in the brain. One class of migraine agents, the triptans, is selective 5-hydroxytryptamine₁ (5-HT₁ or serotonin) receptor agonists. These 5-HT₁ receptor agonists cause constriction of the blood vessels, thereby relieving the pain of a migraine headache. These drugs bind to specific areas on the blood vessels and nerves and stop the inflammation and pain. While they are very effective in relieving migraine headaches, they do not prevent or reduce the number of headaches if taken prophylactically.

Dihydroergotamine is an ergotamine derivative. Ergotamine derivatives exert their effects in the same manner as the triptans but are nonspecific in their binding capabilities (to blood vessels). Therefore, dihydroergotamine may have slightly more side effects. The therapeutic effect of dihydroergotamine is generally attributed to the agonist effect at serotonin receptors. Dihydroergotamine is also effective for prolonged headaches.

Butorphanol and its major metabolites are agonists at the K-opioid receptors and mixed agonist-antagonists at the μ -opioid receptors. While they mask the pain of migraine headaches, they do not stop the headaches.

Policy Guideline Inclusion

An **increased quantity of a migraine agent** is approved when **all** of the following inclusion criteria are met:

- There is a documented diagnosis of migraine headaches.
- There has been a trial of prophylactic treatment with beta blockers, calcium channel blockers, tricyclic antidepressants, valproic acid, methylsergide, or cyproheptadine.
- The requested quantity does not exceed the manufacturer-recommended maximum daily doses.
- The individual has been examined by a neurologist within the past three years.

Policy Guideline Exclusion

An **increased quantity of a migraine agent** is denied when **any** of the following exclusion criteria are present:

- There is no documented diagnosis of migraine headaches.
- There has been no trial of prophylactic treatment with beta blockers, calcium channel blockers, tricyclic antidepressants, valproic acid, methylsergide, or cyproheptadine.
- The requested quantity exceeds the manufacturer-recommended maximum daily doses.
- The individual has not been examined by a neurologist within the past three years.

An urgent, temporary, 96-hour supply of the migraine agent is available (through retail pharmacy facilitation) upon request during review for medical necessity. Refer to Policy List of Applicable Drugs for a list of the migraine quantity limits.

Policy List of Applicable Drugs

Medication	Dosage Form	Quantity Limit (within 30 days)
5HT Receptor Agonists ("triptans")		
Amerge® (naratriptan)	1 mg tablets	23 tablets
Amerge® (naratriptan)	2.5 mg tablets	9 tablets
Axert® (almotriptan)	6.25 mg tablets	24 tablets
Axert® (almotriptan)	12.5 mg tablets	12 tablets
Frova (frovatriptan)	2.5 mg tablets	18 tablets
Imitrex® (sumatriptan)	4 mg injections	14 kits (28 injections)
Imitrex® (sumatriptan)	6 mg injections	9 kits (18 injections)
Imitrex® (sumatriptan)	25 mg tablets	72 tablets
Imitrex® (sumatriptan)	50 mg tablets	36 tablets
Imitrex® (sumatriptan)	100 mg tablets	18 tablets
Imitrex® (sumatriptan)	5 mg nasal spray	72 units
Imitrex® (sumatriptan)	20 mg nasal spray	18 units
Maxalt® and Maxalt MLT® (rizatriptan)	5 mg tablets	24 tablets
Maxalt® and Maxalt MLT® (rizatriptan)	10 mg tablets	12 tablets
Relpax® (eletriptan HBr)	20 mg tablets	24 tablets
Relpax® (eletriptan HBr)	40 mg tablets	12 tablets
Treximet™ (Sumatriptan and naproxen sodium)	Sumatriptan 85 mg, naproxen sodium 500 mg tablets	18 tablets
Zomig® and Zomig ZMT® (zolmitriptan)	2.5 mg tablets	18 tablets
Zomig® and Zomig ZMT® (zolmitriptan)	5 mg tablets	9 tablets
Zomig NS® (zolmitriptan)	5 mg nasal spray	9 units
Other Migraine Agents		

Migranal® (dihydroergotamine)	4 mg nasal spray	One 8-dose package (8 mL)
Stadol NS® (butorphanol)	10 mg nasal spray	4 units

This list is subject to change as new products are introduced to the market.

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References

Amerge® (naratriptan hydrochloride) [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2007. Also available online at: http://us.gsk.com/products/assets/us_amerige.pdf Accessed April 1, 2009.

Axert® (almotriptan malate) [package insert]. Raritan, NJ: OrthoMcNeil Pharmaceutical, Inc.; 2007. Also available online at: <http://www.axert.com/axert/assets/axertpi.pdf> Accessed March 20, 2008. Accessed April 1, 2009.

Frova® (frovatriptan succinate) [package insert]. Chadds Ford, PA: Endo Pharmaceuticals, Inc.; 2007. Also available only at: http://www.endo.com/pdf/Frova_PI_March_2007.pdf Accessed April 1, 2009.

Imitrex® (sumatriptan) Nasal Spray [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2007. Also available online at: http://us.gsk.com/products/assets/us_imitrex_nasal_spray.pdf Accessed April 1, 2009.

Imitrex® (sumatriptan succinate) [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2007. Also available online at: http://us.gsk.com/products/assets/us_imitrex_tablets.pdf Accessed April 1, 2009.

Lee D. Migraine headaches [MedicineNet Web site]. 03/23/07. Available at: <http://www.focusonmigraine.com/script/main/art.asp?articlekey=417&rd=1> Accessed April 1, 2009.

Maxalt® (rizatriptan benzoate) [package insert]. Whitehouse Station, NJ: Merck & Co, Inc; 2008. Also available online at: http://www.merck.com/product/usa/pi_circulars/m/maxalt/maxalt_pi.pdf Accessed April 1, 2009.

Migranal® (dihydroergotamine mesylate) Nasal Spray [package insert]. Costa Mesa, CA: Valeant Pharmaceuticals; 2007. Also available online at: http://prescriptionmigrainerelief.com/HTML-INF/6_0_Prescribing_Info/migranal_PI.pdf Accessed April 1, 2009.

Relpax® (eletriptan hydrobromide) [package insert]. New York, NY: Roerig (Pfizer Inc); 2008. Also available online at: http://www.pfizer.com/pfizer/download/uspi_relpax.pdf Accessed April 1, 2009.

Treximet™ (sumatriptan succinate and naproxen sodium). [package insert]. Research Triangle Park, NC: GlaxoSmithKline; July 2008. Also available online at: http://us.gsk.com/products/assets/us_treximet.pdf Accessed April 1, 2009.

Zomig® (zolmitriptan) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2008. Also available online at: <http://www1.astrazeneca-us.com/pi/Zomig.pdf> Accessed April 1, 2009.

Policy Link to Related Policies

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