

Pharmacy Policy Bulletin

Title: Migraine and Headache Agents

Policy #: Rx.01.251

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

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. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. 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.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **rizatriptan (Maxalt®/Maxalt® MLT), naratriptan (Amerge®), frovatriptan (Frova®), sumatriptan (Imitrex®, Tosymra®, Onzetra® Xsail, Zembrace® Symtouch), eletriptan (Relpax®), zolmitriptan (Zomig®/ Zomig® ZMT), sumatriptan/naproxen (Treximet®), dihydroergotamine mesylate (D.H.E. 45®, Migranal®, Trudhesa™), Rimegepant (Nurtec™ ODT), ubrogepant (Ubrelvy™), lasmiditan (Reyvow®), erenumab (Aimovig™), fremanezumab (Ajovy™), galcanezumab (Emgality™)** as provided under the member's prescription drug benefit.

Description:

Migraine is a common primary headache disorder of unclear etiology. It is recurrent in nature and classically presents as moderate-to-severe head pain lasting 4-72 hours. Calcitonin gene-related peptide (CGRP) and pituitary adenylate cyclase-activating polypeptide (PACAP) may play important roles in mediating migraine attacks.

Rizatriptan binds with high affinity to human cloned 5-HT_{1B} and 5-HT_{1D} receptors. Rizatriptan has weak affinity for other 5-HT₁ receptor subtypes (5-HT_{1A}, 5-HT_{1E}, 5-HT_{1F}) and the 5-HT₇ receptor, but has no significant activity at 5-HT₂, 5-HT₃, alpha- and beta-adrenergic, dopaminergic, histaminergic, muscarinic or benzodiazepine receptors. The therapeutic activity of rizatriptan in migraine can most likely be attributed to agonist effects at 5-HT_{1B/1D} receptors on the extracerebral, intracranial blood vessels that become dilated during a migraine attack and on nerve terminals in the trigeminal system. Activation of these receptors results in cranial vessel constriction, inhibition of neuropeptide release and reduced transmission in trigeminal pain pathways.

MAXALT® and MAXALT-MLT® are indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years old.

Naratriptan binds with high affinity to human cloned 5-HT_{1B/1D} receptors. The therapeutic activity of AMERGE for the treatment of migraine headache is thought to be due to the agonist effects at the 5-HT_{1B/1D} receptors on intracranial blood vessels (including the arterio-venous anastomoses) and sensory nerves of the trigeminal system, which result in cranial vessel constriction and inhibition of pro-inflammatory neuropeptide release.

AMERGE is indicated for the acute treatment of migraine with or without aura in adults.

Frovatriptan binds with high affinity to 5-HT_{1B/1D} receptors. The therapeutic activity of FROVA is thought to be due to the agonist effects at the 5-HT_{1B/1D} receptors on intracranial blood vessels (including the arterio-venous anastomoses) and sensory nerves of the trigeminal system which result in cranial vessel constriction and inhibition of pro-inflammatory neuropeptide release.

FROVA is indicated for the acute treatment of migraine with or without aura in adults.

Sumatriptan binds with high affinity to human cloned 5-HT_{1B/1D} receptors. Sumatriptan presumably exerts its therapeutic effects in the treatment of migraine and cluster headaches through agonist effects at the 5-HT_{1B/1D}

receptors on intracranial blood vessels and sensory nerves of the trigeminal system, which result in cranial vessel constriction and inhibition of pro-inflammatory neuropeptide release.

IMITREX injection is indicated in adults for (1) the acute treatment of migraine, with or without aura, and (2) the acute treatment of cluster headache.

TOSYMRA is indicated for the acute treatment of migraine with or without aura in adults.

ONZETRA® Xsail® is indicated for the acute treatment of migraine with or without aura in adults.

ZEMBRACE SymTouch is indicated for the acute treatment of migraine with or without aura in adults.

Eletriptan binds with high affinity to 5-HT_{1B}, 5-HT_{1D} and 5-HT_{1F} receptors, has modest affinity for 5-HT_{1A}, 5-HT_{1E}, 5-HT_{2B} and 5-HT₇ receptors. The therapeutic activity of RELPAX for the treatment of migraine headache is thought to be due to the agonist effects at the 5-HT_{1B/1D} receptors on intracranial blood vessels (including the arterio-venous anastomoses) and sensory nerves of the trigeminal system which result in cranial vessel constriction and inhibition of pro-inflammatory neuropeptide release.

RELPAX is indicated for the acute treatment of migraine with or without aura in adults.

Zolmitriptan binds with high affinity to human recombinant 5-HT_{1D} and 5-HT_{1B} receptors, and moderate affinity for 5-HT_{1A} receptors. The N-desmethyl metabolite also has high affinity for 5-HT_{1B/1D} and moderate affinity for 5-HT_{1A} receptors.

ZOMIG is indicated for the acute treatment of migraine with or without aura in adults.

ZOMIG Nasal Spray is indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.

TREXIMET contains sumatriptan and naproxen. Sumatriptan binds with high affinity to cloned 5-HT_{1B/1D} receptors. Sumatriptan presumably exerts its therapeutic effects in the treatment of migraine headache through agonist effects at the 5-HT_{1B/1D} receptors on intracranial blood vessels and sensory nerves of the trigeminal system, which result in cranial vessel constriction and inhibition of neuropeptide release. TREXIMET has analgesic, anti-inflammatory, and antipyretic properties. The mechanism of action of TREXIMET, like that of other NSAIDs, is not completely understood but involves inhibition of cyclooxygenase (COX-1 and COX-2).

TREXIMET is indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.

Dihydroergotamine binds with high affinity to 5-HT_{1Dα} and 5-HT_{1Dβ} receptors. It also binds with high affinity to serotonin 5-HT_{1A}, 5-HT_{2A}, and 5-HT_{2C} receptors, noradrenaline α_{2A}, α_{2B} and α₁ receptors, and dopamine D_{2L} and D₃ receptors. The therapeutic activity of dihydroergotamine in migraine is generally attributed to the agonist effect at 5-HT_{1D} receptors.

D.H.E. 45 (dihydroergotamine mesylate) Injection, USP is indicated for the acute treatment of migraine headaches with or without aura and the acute treatment of cluster headache episodes.

MIGRANAL® and TRUDHESA™ (dihydroergotamine mesylate) Nasal Spray is indicated for the acute treatment of migraine headaches with or without aura.

Rimegepant is a calcitonin gene-related peptide receptor antagonist.

NURTEC ODT is indicated for the acute treatment of migraine with or without aura in adults and for the preventive treatment of episodic migraine in adults.

Ubrogepant is a calcitonin gene-related peptide receptor antagonist.

UBRELVY is indicated for the acute treatment of migraine with or without aura in adults.

Lasmiditan binds with high affinity to the 5-HT_{1F} receptor. Lasmiditan presumably exerts its therapeutic effects in the treatment of migraine through agonist effects at the 5-HT_{1F} receptor; however, the precise mechanism is unknown.

REYVOW® is indicated for the acute treatment of migraine with or without aura in adults.

Erenumab-aooe is a human monoclonal antibody that binds to the calcitonin gene-related peptide (CGRP) receptor and antagonizes CGRP receptor function.

AIMOVIG is indicated for the preventive treatment of migraine in adults.

Fremanezumab-vfrm is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor.

AJOVY is indicated for the preventive treatment of migraine in adults.

Cluster headache is an uncommon primary headache disorder characterized by attacks of severe unilateral pain with ipsilateral autonomic symptoms. Pathophysiology is unclear; proposed mechanisms involve interaction of trigeminal nerve (TN) and trigeminovascular system, parasympathetic nerve fibers (trigeminal autonomic reflex), and hypothalamus.

Galcanezumab-gnlm is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor.

EMGALITY is indicated for the preventive treatment of migraine in adults and for the treatment of episodic cluster headache in adults.

Policy:

Acute Treatment of Migraine

INITIAL CRITERIA Brand Maxalt®/Maxalt® MLT, Amerge®, Frova®, Imitrex®, Tosymra®, Relpax®, Onzetra® Xsail, Zembrace® Symtouch, zolmitriptan nasal spray, or Zomig®/zolmitriptan Zomig® ZMT is approved when ALL of the following inclusion criteria are met:

1. Diagnosis of migraine headache; and
2. Use in the age group shown in the table below; and
3. Inadequate response or inability to tolerate two generic triptans (e.g., eletriptan, naratriptan, rizatriptan, zolmitriptan, sumatriptan) as appropriate for the member's age

Drug	Age Recommendation
Rizatriptan (Maxalt®/Maxalt® MLT)	Age 6 and up
Zolmitriptan (Zomig®/Zomig® ZMT)	Age 12 and up
Eletriptan (Relpax®)	Age 18 and up
Naratriptan (Amerge®)	Age 18 and up
Sumatriptan (Imitrex®, Onzetra® Xsail, Zembrace® Symtouch, Tosymra®)	Age 18 and up
Frovatriptan (Frova®)	Age 18 and up

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Brand Maxalt®/Maxalt® MLT, Amerge®, Frova®, Imitrex®, Tosymra®, Relpax®, Onzetra® Xsail, Zembrace® Symtouch, zolmitriptan nasal spray or Zomig®/Zomig® ZMT is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

INITIAL CRITERIA Sumatriptan/naproxen (Treximet®) is approved when ALL of the following are met:

1. Diagnosis of migraine headache; and
2. Member is 12 years of age or older; and
3. Inadequate response or inability to tolerate three generic triptans (e.g., eletriptan, naratriptan, rizatriptan, zolmitriptan, sumatriptan); and
4. Inadequate response to concurrent administration of sumatriptan and naproxen as separate products

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Sumatriptan/naproxen (Treximet®) is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

INITIAL CRITERIA Dihydroergotamine mesylate (D.H.E. 45®) injection is approved when ALL of the following are met:

1. Prescribed by or in consultation with one of the following specialists:
 - a. Neurologist; or
 - b. Pain specialist; or
 - c. Headache specialist certified by the United Council of Neurologic Subspecialties; and
2. Diagnosis of migraine or cluster headaches; and
3. Member is 18 years of age or older; and
4. Member has been instructed on proper preparation, injection, and disposal of medication; and
5. ONE of the following:
 - a. Inadequate response or inability to tolerate an injectable triptan; or
 - b. Triptan overuse, defined as using triptans greater than 8 days per month; and
6. For brand D.H.E. 45 only, inadequate response or inability to tolerate generic dihydroergotamine injection or it is not available

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Dihydroergotamine mesylate (D.H.E. 45®) injection is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

INITIAL CRITERIA Dihydroergotamine mesylate (Migranal®) or dihydroergotamine mesylate HFA (Trudhesa™) is approved when ALL of the following are met:

1. Diagnosis of moderate to severe migraine headache with or without aura; and
2. Inadequate response or inability to tolerate TWO, oral or nasal, triptans; and
3. Prescribed by or in consultation with one of the following specialists:
 - a. Neurologist; or
 - b. Pain specialist; or
 - c. Headache specialist certified by the United Council of Neurologic Subspecialties

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Dihydroergotamine mesylate (Migranal®) or dihydroergotamine mesylate HFA (Trudhesa™) is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

INITIAL CRITERIA Rimegepant (Nurtec™ ODT), ubrogepant (Ubrelvy™) or lasmiditan (Reyvow®) is approved when all of the following criteria are met:

1. Diagnosis of migraine with or without aura; and
2. Will be used for the acute treatment of migraine; and
3. Will not be used for preventative treatment of migraine; and
4. Member has fewer than 15 headache days per month; and
5. Member is 18 years of age or older; and
6. Inadequate response or inability to tolerate two triptans (e.g., eletriptan, rizatriptan, sumatriptan); and
7. If the member has 4 or more headache days per month, the member must be on current treatment or have inability to tolerate one of the following:
 - a. Elavil (amitriptyline) or Effexor (venlafaxine); or
 - b. Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate); or
 - c. Beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol); and
8. Prescribed by or in consultation with one of the following specialists:
 - a. Neurologist; or
 - b. Pain specialist; or
 - c. Headache specialist certified by the United Council of Neurologic Subspecialties; and
9. Medication will not be used in combination with another oral CGRP antagonist; and
10. For Lasmiditan (Reyvow®) only, inadequate response or inability to tolerate BOTH rimegepant (Nurtec™ ODT) and ubrogepant (Ubrelvy™)

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Rimegepant (Nurtec™ ODT), ubrogepant (Ubrelyv™) or lasmiditan (Reyvow®) is reapproved when all of the following criteria are met:

1. Member has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea); and
2. Will not be used for preventative treatment of migraine; and
3. Prescribed by or in consultation with one of the following specialists:
 - a. Neurologist; or
 - b. Pain specialist; or
 - c. Headache specialist certified by the United Council of Neurologic Subspecialties; and
4. Medication will not be used in combination with another oral CGRP antagonist

Reauthorization duration: 2 years

Preventative Treatment of Episodic or Chronic Migraine with Injectable CGRP Antagonists

INITIAL CRITERIA Erenumab (Aimovig™), fremanezumab (Ajovy™), or galcanezumab (Emgality™) 120mg/ml is approved when ALL of the following are met:

1. Prescribed by or in consultation with one of the following specialists:
 - a. Neurologist; or
 - b. Pain specialist; or
 - c. Headache specialist certified by the United Council for Neurologic Subspecialties, and
2. Member is 18 years of age or older; and
3. ONE of the following:
 - a. Diagnosis of episodic migraines defined as 5-14 headache days per month and inadequate response or inability to tolerate at least a two-month trial of TWO of the following prophylactic medications:
 - i. Topiramate
 - ii. Divalproex sodium/ valproic acid
 - iii. Beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol
 - iv. Tricyclic antidepressants: amitriptyline, nortriptyline
 - v. SNRI antidepressants: venlafaxine, duloxetine; or
 - b. Diagnosis of chronic migraines defined as 15 or more headache days per month and inadequate response or inability to tolerate at least a two-month trial of TWO of the following prophylactic medications:
 - i. Topiramate
 - ii. Divalproex sodium/ valproic acid
 - iii. Beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol
 - iv. Tricyclic antidepressants: amitriptyline, nortriptyline
 - v. SNRI antidepressants: venlafaxine, duloxetine
 - vi. Trial of additional prophylactic medications does not apply if member has previously been treated with onabotulinumtoxin A (Botox) for migraines
4. For Fremanezumab (Ajovy™) only, inadequate response or inability to tolerate BOTH erenumab (Aimovig™) and galcanezumab (Emgality™) 120mg/ml.

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Erenumab (Aimovig™), fremanezumab (Ajovy™), or galcanezumab (Emgality™) 120mg/ml is re-approved when ALL of the following are met:

1. Prescribed by or in consultation with one of the following specialists:
 - a. Neurologist; or
 - b. Pain specialist; or
 - c. Headache specialist certified by the United Council for Neurologic Subspecialties, and
2. Documentation of response to therapy as defined by 50% reduction in headache days per month from baseline (defined as at least 4 hours duration and moderate intensity)

Reauthorization duration: 12 months

Preventative Treatment of Episodic Migraines with Oral CGRP Antagonist

INITIAL CRITERIA Rimegepant (Nurtec™ ODT) is approved when all of the following criteria are met:

1. Both of the following:
 - a. Diagnosis of episodic migraines; and
 - b. Member has 4 to 18 migraine days per month, but no more than 18 headache days per month; and
2. Member is 18 years of age or older; and
3. Two of the following:
 - a. Inadequate response or inability to tolerate at least a two-month trial of Elavil (amitriptyline) or Effexor (venlafaxine); or
 - b. Inadequate response or inability to tolerate at least a two-month trial of Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate); or
 - c. Inadequate response or inability to tolerate at least a two-month trial of one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol; and
4. Prescribed by or in consultation with one of the following specialists:
 - a. Neurologist; or
 - b. Pain specialist; or
 - c. Headache specialist certified by the United Council for Neurologic Subspecialties; and
5. Medication will not be used in combination with an injectable CGRP antagonist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Rimegepant (Nurtec™ ODT) is re-approved when all of the following criteria are met:

1. Member has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity; and
2. Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy; and
3. Prescribed by or in consultation with one of the following specialists:
 - a. Neurologist; or
 - b. Pain specialist; or
 - c. Headache specialist certified by the United Council for Neurologic Subspecialties; and
4. Medication will not be used in combination with an injectable CGRP antagonist

Reauthorization duration: 2 years

Episodic Cluster Headaches

INITIAL CRITERIA Galcanezumab (Emgality™) 100mg/ml is approved when ALL of the following are met:

1. Diagnosis of episodic cluster headache; and
2. Member has experienced at least 2 cluster periods lasting 7 days to 365 days, separated by pain-free periods lasting at least three months; and
3. Member is 18 years of age or older; and
4. Prescribed by or in consultation with one of the following specialists:
 - a. Neurologist; or
 - b. Pain specialist; or
 - c. Headache specialist certified by united council for neurologic subspecialties, or pain specialist; and
5. Medication will not be used in combination with another CGRP antagonist

Initial authorization duration: 3 months

REAUTHORIZATION CRITERIA Galcanezumab (Emgality™) 100mg/ml is re-approved when ALL of the following are met:

1. Member has experienced a positive clinical response to therapy, demonstrated by a reduction in headache frequency and/or intensity; and
2. Prescribed by or in consultation with one of the following specialists:
 - a. Neurologist; or
 - b. Pain specialist; or
 - c. Headache specialist certified by united council for neurologic subspecialties, or pain specialist
3. Medication will not be used in combination with another CGRP antagonist

Reauthorization duration: 12 months

Black Box Warning as shown in the drug Prescribing Information:

Migranal®, D.H.E 45®, Trudhesa™

WARNING: PERIPHERAL ISCHEMIA FOLLOWING COADMINISTRATION WITH POTENT CYP3A4 INHIBITORS
Serious and/or life-threatening peripheral ischemia has been associated with the coadministration of dihydroergotamine with strong CYP3A4 inhibitors. Because CYP3A4 inhibition elevates the serum levels of dihydroergotamine, the risk for vasospasm leading to cerebral ischemia and/or ischemia of the extremities is increased. Hence, concomitant use of TRUDHESA with strong CYP3A4 inhibitors is contraindicated.

Treximet®

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.

TREXIMET is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

Guidelines:

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

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

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Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Maxalt®/Maxalt® MLT	Rizatriptan
Amerge®	Naratriptan
Frova®	Frovatriptan

Imitrex®, Tosymra®, Onzetra® Xsail, Zembrace® Symtouch	Sumatriptan
Relpax®	Eletriptan
Zomig®/ Zomig® ZMT	Zolmitriptan
Treximet®	Sumatriptan/naproxen
D.H.E. 45®, Migranal®, Trudhesa™	Dihydroergotamine mesylate
Nurtec™ ODT	Rimegepant
Ubrelvy™	Ubrogepant
Reyvow®	Lasmiditan
Aimovig™	Erenumab
Ajovy™	Fremanezumab
Emgality™	Galcanezumab

Cross References:

Rx.01.33 Off Label Use

Rx.01.76 Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit

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