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DRUG POLICY

5-HT1 Serotonin Receptor Agonists (Triptans)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the 5-HT1 Serotonin Receptor Agonists (Triptans) criteria is to ensure appropriate therapy selection according to the Food and Drug Administration (FDA)-approved product labeling and/or clinical guidelines and/or clinical trials. The criteria will encourage the use of preferred generic triptans first and ensure quantity limits are not exceeded based on FDA-approved maximum daily dosing and product packaging.

The anti-migraine agents in this policy are all part of the 5-HT1 Serotonin Receptor Agonist class of drugs, also known as the Triptans class. Triptans are believed to effect migraine relief by binding to serotonin (5-hydroxy-tryptamine) receptors in the brain, where they act to induce vasoconstriction of extracerebral blood vessels and also reduce neurogenic inflammation.

POLICY

Criteria for Initial Approval

- I. Brand and generic Axert (Almotriptan), brand and generic Frova (frovatriptan), and brand and generic Relpax (eletriptan) may be considered **medically necessary** when the following criteria is met:
 - The patient has had an inadequate treatment response after at least a 30 day trial of or is intolerant to at least THREE of the following preferred generic triptan medications unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs):
 - naratriptan (Amerge)
 - sumatriptan (Imitrex)

- rizatriptan (Maxalt)
- zolmitriptan (Zomig)
- sumatriptan (Imitrex) nasal spray

Approval will be for lifetime.

II. Sumatriptan (Imitrex) subcutaneous injection may be considered **medically necessary** when the following criteria is met:

- The patient has had an inadequate treatment response after at least a 30 day trial of or is intolerant to BOTH an oral and nasal formulation of a triptan medication unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

Approval will be for lifetime.

III. Tosymra (sumatriptan) nasal spray may be considered **medically necessary** when the following criteria is met:

- Patient has a diagnosis of migraine (with or without aura); AND
 - The patient has had an inadequate treatment response after at least a 30 day trial of or is intolerant to at least ONE of the following preferred oral generic triptan medications unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs):
 - naratriptan (Amerge)
 - sumatriptan (Imitrex)
 - rizatriptan (Maxalt)

AND

- The patient has had an inadequate treatment response after at least a 30 day trial of or is intolerant to sumatriptan (Imitrex) nasal spray

Approval will be for lifetime.

IV. Zomig (zolmitriptan) nasal spray may be considered **medically necessary** when the following criteria is met:

- Patient has a diagnosis of migraine (with or without aura); AND
 - The patient has had an inadequate treatment response after at least a 30 day trial of or is intolerant to at least ONE of the following preferred oral generic triptan medications unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs):
 - naratriptan (Amerge)
 - sumatriptan (Imitrex)
 - rizatriptan (Maxalt)

AND

- The patient has had an inadequate treatment response after at least a 30 day trial of or is intolerant to Zolmitriptan (Zomig) oral

AND

- The patient has had an inadequate treatment response after at least a 30 day trial of or is intolerant to sumatriptan (Imitrex) nasal spray unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs):

OR

- The patient has a diagnosis of cluster headache; AND
 - The patient has had an inadequate treatment response after at least a 30 day trial of or is intolerant to BOTH of the following unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs):
 - sumatriptan (Imitrex) nasal spray
 - sumatriptan (Imitrex) subcutaneous injection

Approval will be for lifetime.

V. Treximet (sumatriptan + naproxen) may be considered **medically necessary** when ALL of the following criteria are met:

- Patient is 12 years of age or older
- Patient has a diagnosis of migraine headaches (with or without aura)
- Patient must try and fail a therapeutic trial of sumatriptan and naproxen as separate products taken at the same time. Treatment failure cannot be caused by a lack of compliance to therapy or the unwillingness to take sumatriptan and naproxen separately.

Approval will be for lifetime.

VI. Prior authorization is not required for Imitrex (excluding injectable formulations), sumatriptan (excluding Tosymra and injectable formulations), Amerge, naratriptan, Maxalt, Maxalt MLT, rizatriptan, Zomig, Zomig ZMT or zolmitriptan.

Medications on this policy are considered **not medically necessary** for patients who do not meet the criteria set forth above.

Quantity Limits

QUANTITY LIMIT CHART				
Brand Name	Generic Name	Dose	Max Dose	Quantity Limit
Amerge & naratriptan	naratriptan	Tablet: 1mg, 2.5mg	5mg/24hr.	18 tablets/30 days
Axert & almotriptan	almotriptan	Tablet: 6.25mg, 12.5mg	25mg/24hr.	18 tablets/30 days
Frova & frovatriptan	frovatriptan	Tablet: 2.5mg	7.5mg/24hr.	27 tablets/30 days
Imitrex & sumatriptan	sumatriptan	Tablet: 25mg, 50mg, 100mg	200mg/24hr.	18 tablets/30 days
Imitrex & sumatriptan injectable	sumatriptan	Injection: 4mg/0.5ml,	12mg/24hr.	27 injections/30 days
		6mg/0.5ml		18 injections/30 days
Imitrex & sumatriptan nasal spray	sumatriptan	Nasal spray: 5mg	40mg/24hr.	36 bottles/30 days
		20mg		18 bottles/30 days
Maxalt & rizatriptan	rizatriptan	Tablet: 5mg, 10mg	30mg/24hr.	27 tablets/30 days
Maxalt MLT & rizatriptan ODT		Oral disintegrating tablet: 5mg, 10mg		
Relpax & eletriptan	eletriptan	Tablet: 20mg, 40mg	80mg/24hr.	18 tablets/30 days
Tosymra	sumatriptan	Nasal spray: 10mg	30mg/24hr.	18 units/30 days
Treximet	sumatriptan + naproxen	10mg/60mg 85mg/500mg	2 tab/24 hr.	9 tablets/30 days

Zomig & zolmitriptan	zolmitriptan	Tablet: 2.5mg,5mg	10mg/24hr.	18 tablets/30 days
Zomig ZMT & zolmitriptan ODT		Oral disintegrating tablet: 2.5mg,5mg		
Zomig nasal spray	zolmitriptan	Nasal spray: 2.5, 5mg/spray	10mg/24hr	18 units/30 days

CLINICAL RATIONALE

The intent of the criteria is to encourage the use of preferred generic triptans first and provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Amerge, Axert, Frova, Imitrex, Maxalt/Maxalt-MLT, Relpax, Sumavel DosePro, Treximet, and Zomig/Zomig-ZMT are indicated for the acute treatment of migraine attacks with or without aura. Axert and Treximet are indicated for the acute treatment of migraine headache pain with or without aura in adolescents ages 12 to 17 years. Maxalt-MLT and Maxalt are indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 6 to 17 years old. 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. Imitrex Injection and Sumavel DosePro are indicated for the acute treatment of cluster headache episodes. Additionally, Imitrex Nasal Spray and Zomig Nasal Spray have a level A recommendation for the treatment of cluster headaches per American Headache Society treatment guidelines.

Triptan therapy is contraindicated in patients with confirmed or suspected cardiovascular disease (e.g., ischemic or vasospastic coronary artery disease) or cerebrovascular disease (e.g., stroke or transient ischemic attacks), and in patients with uncontrolled hypertension.

Frequent use of acute migraine drugs (e.g. ergotamine, triptans, opioids, or combination of these drugs for 10 or more days per month) may lead to exacerbation of headache (medication overuse headache). To decrease the risk of medication-overuse headache (“rebound headache” or “drug-induced headache”) many experts limit acute therapy to two headache days per week on a regular basis. Therefore, the prescriber must have considered and ruled out the diagnosis of medication overuse headache; and, the limits are set at a quantity sufficient to treat 8 headaches per month and may allow for up to 9 headache days per month up to maximum recommended daily dosing, contingent on package dispensing requirements. Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated in Quantity Limit column in the Quantity Limit chart.

For prevention of migraine headache, the American Academy of Neurology and the American Headache Society 2012 guideline update recommendations state that the following medications are established as effective and should be offered for migraine prevention: β -adrenergic blocking agents, metoprolol, propranolol, timolol; and antiepileptic drugs (AEDs), divalproex sodium, topiramate, sodium valproate. Additionally the following medications are probably effective: antidepressants, amitriptyline, venlafaxine; and β -adrenergic blocking agents, atenolol, nadolol and should be considered for migraine prevention. Efficacy and safety of individual agents, even within the same class of drugs, may vary among patients therefore, if the patient fails one preventive medication, others should be tried as failure of one agent does not preclude success with another one. Therefore, patients with migraine headache must be currently taking or had inadequate response, intolerance, or contraindication to prophylactic therapies.

Cluster headache is a most painful form of primary headache lasting 15 to 180 minutes, occurring from once every other day to eight times per day, and associated with one or more of various ipsilateral symptoms (conjunctival injection, lacrimation, nasal congestion, rhinorrhea, forehead and facial sweating,

miosis, ptosis or eyelid edema). Preventative treatment of cluster headache aims to decrease the incidence of attacks while acute therapy is directed at alleviating the symptoms of an individual attack when it occurs. Given the severity, fast onset and short time to peak intensity of this type of headache, treatment should be rapid and effective. The treatments of choice for acute cluster headache attacks are oxygen, and intranasal or subcutaneous sumatriptan or intranasal zolmitriptan, or a combination of both. Imitrex injection, Imitrex Nasal Spray, Sumavel DosePro and Zomig Nasal Spray will also be considered for patients with cluster headache who require quantities in excess of the initial limit.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Code(s), if applicable.

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POLICY HISTORY

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