



Prior Authorization Approval Criteria

Treximet (sumatriptan/naproxen sodium)

| | |
|---|---|
| Generic name: | sumatriptan/naproxen sodium |
| Brand name: | Treximet |
| Medication class: | Serotonin (5-HT ₁) receptor agonist/NSAID |
| FDA-approved uses: | acute treatment of migraine attacks |
| Available dosage forms: | tablet containing sumatriptan (85 mg) and naproxen sodium (500 mg) (packs of 9 tablets) |
| Usual dose: | The recommended dose is 1 tablet The efficacy of taking a second dose has not been established. Do not take more than 2 Treximet tablets in 24 hours. Dosing of tablets should be at least 2 hours apart. The safety of treating an average of more than 5 migraine headaches in a 30-day period has not been established. |
| Approximate monthly cost: (based on AWP 2009) | \$206.65 (9 tablets) |
| Duration of therapy: | indefinite |

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- Clinically diagnosed migraine headaches
- Failed/ intolerant to 2 FCHP preferred alternative triptan products used alone
- Failed treatment with sumatriptan and naproxen as separate products used at the same time
- 18 years of age or older
- Treatment is for 5 headaches a month or less. If requested quantities are greater than the manufacturer recommendation, the request must be submitted with documentation as to why larger quantities are required, including all applicable criteria as indicated in the "Excess Quantity Limit criteria".

Contraindication:

- History, symptoms, or signs of ischemic cardiac, cerebrovascular, or peripheral vascular syndromes.
- Other significant underlying cardiovascular diseases
- Coronary artery bypass graft (CABG) surgery
- Uncontrolled hypertension.
- Within 24 hrs of ergot-type drugs or concurrent administration of MAO-A inhibitors or within 2 weeks of discontinuing MAOIs or within 24 hours of another 5-HT₁ agonist
- Basilar headaches or hemiplegic migraine
- Hepatic impairment
- Allergy to naproxen/asthma, nasal polyps, urticaria, and hypotension associated with nonsteroidal anti-inflammatory drugs
- Hypersensitivity to sumatriptan or naproxen or any of Treximet's components

Not approved if:

- Patient does not meet the above stated criteria.
- Patient has any contraindications to the use of Treximet, sumatriptan or naproxen.
- Being used for prophylactic therapy of migraine or for cluster headache
- Patients with advanced renal disease or in late pregnancy

Special considerations:

- Treximet is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine
- Safety and effectiveness of Treximet have not been established for cluster headache.
- Treatment with Treximet is not recommended in patients with advanced renal disease (creatinine clearance less than 30 mL/min).
- Treximet should not be used in late pregnancy because NSAID-containing products have been shown to cause premature closure of the ductus arteriosus.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 06/10/09