

Commercial/Healthcare Exchange PA Criteria

Effective: July 25, 2018

Prior Authorization: Sumatriptan succinate/naproxen sodium

Products Affected: sumatriptan succinate/naproxen sodium oral tablet, Treximet oral tablet

Medication Description:

Treximet is a combination of sumatriptan, a serotonin (5-HT) 1b/1d receptor agonist (triptan), and naproxen sodium, a non-steroidal anti-inflammatory drug, indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.

The recommended dosage for adults is 1 tablet of Treximet 85/500 mg. Treximet 85/500 mg contains a dose of sumatriptan higher than the lowest effective dose. The choice of the dose of sumatriptan, and of the use of a fixed combination such as in Treximet 85/500 mg should be made on an individual basis, weighing the possible benefit of a higher dose of sumatriptan with the potential for a greater risk of adverse reactions.

The maximum recommended dosage in a 24-hour period is 2 tablets, taken at least 2 hours apart. The safety of treating an average of more than 5 migraine headaches in adults in a 30-day period has not been established.

Covered Uses: The acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.

Exclusion Criteria:

1. Prevention of migraine attacks
2. Treatment of cluster headache
3. Known hypersensitivity to sumatriptan or naproxen
4. History of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs
5. Ischemic coronary artery disease (CAD) (angina pectoris, history of myocardial infarction, or documented silent ischemia) or coronary artery vasospasm, including Prinzmetal's angina
6. History of stroke or transient ischemic attack (TIA) or history of hemiplegic or basilar migraine
7. Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders
8. Use in the setting of coronary artery bypass graft (CABG) surgery
9. Uncontrolled hypertension
10. Ischemic bowel disease
11. Peripheral vascular disease
12. Severe hepatic impairment
13. Third trimester of pregnancy
14. Concurrent administration of a monoamine oxidase (MAO)-A inhibitor or recent (within 2 weeks) use of an MAO-A inhibitor

Required Medical Information:

1. Diagnosis
2. Medication history

Age Restrictions: 12 years of age and older

Prescriber Restrictions: N/A

Coverage Duration: 6 months

Other Criteria:

- A. The patient has a diagnosis of acute treatment of migraine with or without aura; AND
- B. The patient has had an adequate trial and therapeutic failure of **TWO** prescription strength generic NSAIDs defined as:
 - a. Failure to control symptoms; OR
 - b. Intolerance defined as (but not limited to):
 - i. Allergic reaction
 - ii. Adverse drug reactions; **AND**
- C. The patient has had an adequate trial and therapeutic failure of **TWO** generic selective 5-hydroxytryptamine1 (5-HT1 or serotonin) receptor agonists defined as:
 - a. Failure to control symptoms; OR
 - b. Intolerance defined as (but not limited to):
 - i. Allergic reaction
 - ii. Adverse drug reactions

References:

1. Product Information: TREXIMET(R) oral tablets, sumatriptan naproxen sodium oral tablets. Pernix Therapeutics, LLC (per manufacturer), Morristown, NJ, 2015.
2. Product Information: IMITREX(R) oral tablets, sumatriptan succinate oral tablets. GlaxoSmithKline, Research Triangle Park, NC, 2007.

Policy Revision history:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	3/26/2018

2	Update	<p>Update to include FDA labeled contraindications to therapy</p> <p>CCI Adopted EH Policy, removed from CCI Cambia-Treximet Policy</p> <p>CCI P&T Review History: 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 11/16, 5/17, 5/18, 7/18, 5/19</p> <p>CCI Revision Record: 1/11, 11/16, 5/18, 7/18</p>	<p>Exclusion Criteria</p> <p>Products Affected</p> <p>Other Criteria; ALL</p>	12/27/2019
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