

Commercial/Healthcare Exchange PA Criteria

Effective: July 25, 2018

<u>Prior Authorization:</u> 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.

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

Exclusion Criteria:

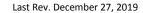
- 1. Prevention of migraine attacks
- 2. Treatment of cluster headache
- 3. Known hypersensitivity to sumatriptan or naproxen
- 4. History of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs
- 5. Ischemic coronary artery disease (CAD) (angina pectoris, history of myocardial 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 <u>TWO</u> 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	Update to include FDA labeled contraindications to therapy CCI Adopted EH Policy, removed from CCI Cambia-Treximet Policy 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 CCI Revision Record: 1/11, 11/16, 5/18, 7/18		12/27/2019
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