Sumatriptan Tablets, Nasal Spray (IMITREX), Nasal Powder (ONZETRA XSAIL), sumatriptan and naproxen sodium (TREXIMET TABLETS)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
The selective serotonin receptor agonists, or “triptans”, are a class of medications that have the ability to stop a migraine. Triptans work by binding to serotonin receptors in the brain. Specifically, per Drug Facts and Comparisons pharmacology of the Serotonin 5-HT1 Receptor Agonists (Triptans): The vascular 5-HT1 receptor subtype is present on the human basilar artery and in the vasculature of isolated human dura mater. Current theories on the etiology of migraine headaches suggest that symptoms are caused by local cranial vasodilation or the release of vasoactive and proinflammatory peptides from sensory nerve endings in an activated trigeminal system. The therapeutic activity of the serotonin 5-HT1 receptor agonists in migraine most likely can be attributed to agonist effects at 5-HT1B/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 (1).

This class of medications has potentially serious side effects, especially when taken in high doses. Life-threatening disturbances of cardiac rhythm and myocardial infarction have been reported, as well as stroke. Excessive use of triptans can lead to medication overuse headache (MOH) (2-5).

Regulatory Status
FDA-approved indication:

**Imitrex & Onzeta Xsail: (2-4)**
Nasal Spray, Nasal Powder and Tablets are serotonin 5HT1B/1D receptor agonist (triptan) indicated for the acute treatment of migraine attacks with or without aura in adults.

**Treximet: (5)**
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 year of age and older.

Imitrex Nasal & Tabs / Onzeta Xsail / Treximet FEP Clinical Rationale
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Limitations of Use: (2-5)

1. Use only after clear diagnosis of migraine has been established.
2. Not indicated for the prophylactic therapy of migraine.

Imitrex tablets, Imitrex nasal spray, Onzentra Xsail and Treximet contraindications include: history of coronary artery disease or coronary vasospasm, Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorder, history of stroke, transient ischemic attack, or hemiplegic or basilar migraine, peripheral vascular disease, ischemic bowel disease, uncontrolled hypertension, recent (within 24 hours) use of another 5-HT1 agonist (e.g., another triptan) or of an ergotamine-containing medication, concurrent or recent (past 2 weeks) use of monoamine oxidase-A inhibitor, and severe hepatic impairment, known hypersensitivity to sumatriptan (angioedema and anaphylaxis seen) (2-5).

Treximet has additional contraindications including: use in the setting of CABG surgery, history of asthma, urticaria, other allergic type reactions, rhinitis, or nasal polyps syndrome after taking aspirin or other NSAID/analgesic drugs, known hypersensitivity to sumatriptan, naproxen, or any components of Treximet (angioedema and anaphylaxis seen), and third trimester of pregnancy (5).

A cardiac evaluation in patients with cardiovascular risk factors should be done prior to initiation of treatment with Treximet. Discontinue Treximet if arrhythmias, cerebral hemorrhage, subarachnoid hemorrhage, stroke, gastrointestinal ischemic reactions, peripheral vasospastic reactions, serotonin syndrome, renal papillary necrosis, serious skin necrosis or elevated liver enzymes and severe hepatic reactions occur. Monitor blood pressure in hypertensive patients. Use with caution in patients with fluid retention or heart failure (5).

Off Label Use:
Triptans have been found to be safe and effective in the pediatric and adolescent population (6).

Summary
Sumatriptan Tablets, Nasal Spray (IMITREX), Nasal Powder (ONZETRA XSAIL),
sumatriptan and naproxen sodium (TREXIMET TABLETS)

Triptans are serotonin (5-HT) receptor agonists that interrupt attacks or episodes of migraine, but do not prevent migraines from happening. This class of medications has potentially serious side effects, especially when taken in high doses. Life-threatening disturbances of cardiac rhythm and myocardial infarction have been reported, as well as stroke. Triptans have been found to be safe and effective in the pediatric and adolescent population (1-6).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of sumatriptan and sumatriptan / naproxen while maintaining optimal therapeutic outcomes.

References