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 headache at its earliest signs. Triptans work by binding to serotonin receptors in the brain. By mimicking the actions of serotonin, triptans cause the blood vessels to constrict and prevent some nerves from transmitting signals to the brain, effectively blocking the pain associated with migraine headaches. Each triptan medication affects a slightly different number of serotonin receptors, but all work in a similar fashion (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).

Regulatory Status
FDA-approved indication:

Imitrex & Onzetra Xsail: (2, 3, 5)
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: (4)
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.

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.

Treximet contraindications include: history of coronary artery disease or coronary vasospasm, history of coronary artery bypass graft surgery, 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 and severe
hepatic impairment (4).

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 (4).

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

Summary
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
   http://headaches.about.com/od/treatmentoptions/p/triptan_profile.htm