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). MOH was previously called rebound headache, drug-induced headache and medication-misuse headache (2).

Regulatory Status
The FDA-approved indications for these products are: (2-5)
- Acute treatment of migraine attacks, with or without aura
- Acute treatment of cluster headache episodes

Limitations of Use: (2-5)
1. Use only after a clear diagnosis of migraine or cluster headache has been established.
2. Not intended for the prophylactic therapy of migraine

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

Imitrex is available in a solution for injection. An autoinjection device is available for use with 4- and 6-mg prefilled syringe cartridges to facilitate self-administration in patients using the 4- or 6-mg dose (2).

Alsuma is sumatriptan solution supplied in a single dose auto-injector for subcutaneous use (3). Sumavel DosePro is a sumatriptan solution supplied in a prefilled single-dose needle free subcutaneous delivery system (3).
Zembrace SymTouch is available as a prefilled, single dose, autoinjector containing 3 mg sumatriptan. With Zembrace SymTouch, the needle penetrates approximately ¼ inch (6 mm). The injection is intended to be given subcutaneously (5).

Sumatriptan injection is contraindicated in patients with a history or current evidence of hemiplegic or basilar migraine because these patients are at a higher risk of stroke (2-5).

**Summary**
Migraine is a chronic, recurrent condition that affects millions of people worldwide. 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 Imitrex, Alsuma, Sumavel DosePro and Zembrace SymTouch while maintaining optimal therapeutic outcomes.

**References**