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).

Regulatory Status
FDA-approved indication: Frova is a serotonin receptor agonist (triptan) indicated for the acute treatment of migraine attacks with or without aura in adults (2).

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

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).

Frova is contraindicated in patients who have a history of coronary artery disease or coronary artery vasospasm. It is also contraindicated in Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders, history of stroke, transient ischemic attack, hemiplegic or basilar migraine, peripheral vascular disease or ischemic bowel disease (2).
Off Label Use:
Triptans have been found to be safe and effective in the pediatric and adolescent population (3).

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 (3).

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

References