RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Lidoderm is a topical treatment option that can be used alone or with other medicines, to treat after-shingles pain, also referred to as post-herpetic neuralgia. Lidoderm penetrates directly into the skin to reach the damaged nerves (caused by shingles) and to help provide relief at the site of the pain (1).

Regulatory Status
FDA-approved indication: Lidoderm is indicated for relief of pain associated with post-herpetic neuralgia. Apply only to intact skin with no blisters (1).

A maximum of 3 patches can be worn at a time for 12 hours on, followed by 12 hours off. Applying the patches for a longer time or using more than 3 patches at a time could result in increased absorption of lidocaine and high blood concentrations, leading to serious side effects. Lidocaine toxicity could be expected at lidocaine blood concentrations above 5 µg/mL (1).

Off Label Uses:
Neuropathic pain: Lidoderm patches have been shown to be effective in treating neuropathic pain of various types as monotherapy and as adjunctive therapy to an analgesic regimen. There is evidence that Lidoderm patches, along with several other analgesics (i.e., gabapentin, opioids, tramadol, tricyclic antidepressants [TCAs]), can be effective as first-line therapy in the management of neuropathic pain (2).

The safety and effectiveness of Lidoderm patches in pediatric patients have not been established (1).

Summary
Lidoderm is a topical treatment option that can be used alone or with other medicines, to treat after-shingles pain, also referred to as post-herpetic neuralgia. Lidoderm should be applied only to intact skin with no blisters. A maximum of 3 patches can be worn at a time for 12 hours on, followed by 12 hours off. Applying the patches for a longer time or using more than 3
patches at a time could result in increased absorption of lidocaine and high blood concentrations, leading to serious side effects. Lidoderm patches have been shown to be effective in treating neuropathic pain of various types as monotherapy and as adjunctive therapy to an analgesic regimen. The safety and effectiveness of Lidoderm patches in pediatric patients have not been established (1).

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

References