LIDODERM PATCHES
Lidoderm Patches (lidocaine patch 5%), ZTLido (lidocaine topical system 1.8%)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Lidoderm and ZTLido are topical treatment options that can be used alone or with other medicines to treat after-shingles pain (also referred to as post-herpetic neuralgia). Lidoderm and ZTLido have the active ingredient of lidocaine. Lidocaine 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(s):

1. Lidoderm (lidocaine patch 5%) is indicated for relief of pain associated with post-herpetic neuralgia. Apply only to intact skin (1).

2. ZTLido (lidocaine topical system) 1.8% is indicated for relief of pain associated with post-herpetic neuralgia (PHN) (2).

Because of the difference in bioavailability of ZTLido compared to Lidoderm (lidocaine patch 5%), a different dosage strength is required to be administered to the patient. One ZTLido (lidocaine topical system) 1.8% provides equivalent lidocaine exposure to one Lidoderm (lidocaine patch 5%) (2).

A maximum of 3 patches of Lidoderm or 3 topical systems of ZTLido can be worn at a time for 12 hours on, followed by 12 hours off. Applying the Lidoderm or ZTLido for a longer time or using more than 3 patches/topical systems 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 (1-2).

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,
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Tramadol, tricyclic antidepressants [TCAs]), can be effective as first-line therapy in the management of neuropathic pain (3).

The safety and effectiveness of Lidoderm patches and ZTLido topical systems in pediatric patients have not been established (1-2).

Summary
Lidoderm and ZTLido are topical treatment options that can be used alone or with other medicines, to treat after-shingles pain, also referred to as post-herpetic neuralgia. A maximum of 3 Lidoderm patches or ZTLido topical systems 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 and ZTLido topical systems in pediatric patients have not been established (1-3).

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

References