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Section:	Prescription Drugs	**Effective Date:**	October 1, 2020
Subsection:	Topical Products	**Original Policy Date:**	April 10, 2015
Subject:	Lidocaine Patches	**Page:**	1 of 4

Last Review Date: September 11, 2020

Lidocaine Patches

Description

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

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

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, 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).

Related policies
Lidocaine Injection, Lidocaine Powder, Lidocaine Topical 5%

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lidocaine patches may be considered **medically necessary** in patients that are 18 years of age and older with post-herpetic neuralgia and neuropathic pain.

Lidocaine patches is considered **investigational** in patients that are less than 18 year of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Neuropathic pain (i.e. post-herpetic neuralgia)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Quantity

Drug	Quantity per 90 days
Lidoderm Patches	270 units per 90 days

Prior - Approval Limits

Quantity

Drug	Quantity per 90 days
Lidoderm Patches	540 units per 90 days

Drug with approved MFE only	Quantity per 90 days
ZTLido Topical Systems	540 units per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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

1. Lidoderm patches [package insert]. Malvern, PA: Endo Pharmaceuticals, Inc.; November 2018.
2. ZTLido [package insert]. San Diego, CA: Scilex Pharmaceuticals Inc;. November 2018.
3. Dworkin RH, O'Connor AB, Audette J, et al. Recommendations for the pharmacological management of neuropathic pain: an overview and literature update. *Mayo Clin Proc.* 2010;85:S3-S14.

Policy History

Date	Action
January 2015	Addition to PA
July 2015	Annual editorial review and reference update
December 2016	Annual editorial review and reference update Policy number change from 5.14.07 to 5.90.07
September 2017	Annual review
June 2018	Annual editorial review and reference update Addition of ZTLido to criteria Change in policy name from Lidoderm Patches to Lidocaine Patches
September 2019	Annual review and reference update
December 2019	Annual review. Moved ZTLido to MFE with PA only
September 2020	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 11, 2020 and is effective on October 1, 2020.