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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity per 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidoderm Patches</td>
<td>270 units per 90 days</td>
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</table>

**Prior - Approval Limits**
Quantity

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity per 90 days</th>
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</thead>
<tbody>
<tr>
<td>Lidoderm Patches</td>
<td>540 units per 90 days</td>
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</table>

<table>
<thead>
<tr>
<th>Drug with approved MFE only</th>
<th>Quantity per 90 days</th>
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</thead>
<tbody>
<tr>
<td>ZTLido Topical Systems</td>
<td>540 units per 90 days</td>
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</tbody>
</table>

**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

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>January 2015</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>July 2015</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>December 2016</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td></td>
<td>Policy number change from 5.14.07 to 5.90.07</td>
</tr>
<tr>
<td>September 2017</td>
<td>Annual review</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td></td>
<td>Change in policy name from Lidoderm Patches to Lidocaine Patches</td>
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<tr>
<td></td>
<td>Addition of ZTLido to criteria</td>
</tr>
<tr>
<td>September 2019</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>December 2019</td>
<td>Annual review. Moved ZTLido to MFE with PA only</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.