

**NC Medicaid  
Outpatient Pharmacy  
Prior Approval Criteria  
Topical Local Anesthetics**

**Medicaid and Health Choice  
Effective Date: September 15, 2010  
Revised Date: November 19, 2020**

**Therapeutic Class Code:** Q5H  
**Therapeutic Class Description:** Topical Local Anesthetics

Medication
Lidoderm 5% Patch and generic lidocaine patch
ZTLido

**Eligible Beneficiaries**

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries.**

**EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age**

**42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the

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beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

**Basic Medicaid and NC Health Choice Billing Guide:** <https://medicaid.ncdhhs.gov/>  
**EPSDT provider page:** <https://medicaid.ncdhhs.gov/>

**Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age**

**EPSDT does not apply to NCHC beneficiaries.** If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

**Criteria (Initial) for lidocaine patch (generic for Lidoderm)**

- **Patient Beneficiary has been** diagnosed with Post-Herpetic Neuralgia.  
**OR**
- Neuropathic pain with a previous documented trial and failure of at least two of the following drug categories: tri-cyclic antidepressants, SSRI's, SNRI's, anticonvulsants, NSAID's or COXII's  
**OR**
- Chronic musculo-skeletal pain (greater than 6 month in duration) with a previous documented trial and failure of at least two of the following drug categories: tri-cyclic antidepressants, SSRI's, SNRI's, anticonvulsants, NSAID's or COXII's  
**AND**
- Prescribed dose within the FDA recommended maximum amount of 3 patches per day and no more than 90 patches per month.

**Criteria (Initial) for Lidoderm patch and ZTLido**

- **Patient Beneficiary has been** diagnosed with Post-Herpetic Neuralgia.  
**OR**
- Neuropathic pain with a previous documented trial and failure of at least two of the following drug categories: tri-cyclic antidepressants, SSRI's, SNRI's, anticonvulsants, NSAID's or COXII's **or beneficiary has a documented clinical reason that these products cannot be tried.**

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**OR**

- Chronic musculo-skeletal pain (greater than 6 month in duration) with a previous documented trial and failure of at least two of the following drug categories: tri-cyclic antidepressants, SSRI's, SNRI's, anticonvulsants, NSAID's or COXII's **or beneficiary has a clinical reason that these products cannot be tried.**

**AND**

- Prescribed dose within the FDA recommended maximum amount of 3 patches per day and no more than 90 patches per month.

**AND**

- **Beneficiary has tried and failed, or has contraindication or intolerance, to preferred lidocaine patch**

**Criteria (Continuation):**

- Beneficiary is showing continued benefit and improvement or stability in functional status.

**Procedures:**

- New prescriptions will be limited to coverage of 1 box (30 patches) upon the first fill. Subsequent refills will be for up to a 34 day supply.
- Length of therapy may be approved for up to 12 months.

**References**

1. Local Anesthetics, Topical. Drug Facts and Comparisons, Drug Facts and Comparisons, Wolters Kluwer Health. St. Louis (MO): updated monthly.
2. Prescriber Information-Lidoderm Patch ® (lidocaine patch 5%), Endo Pharmaceuticals, Inc., Chadds Ford, Pennsylvania 19317. March 2010.
3. Gold Standard, Inc. Lidoderm. *Clinical Pharmacology* [database online]. Available at: <http://www.clinicalpharmacology.com>. Accessed April 12, 2011.
4. Jefferies, K. Treatment of Neuropathic Pain. *Semin Neurol*. 2010; 30(4):425-432. <http://www.medscape.com/viewarticle/730671> Accessed April 12, 2011.
5. Attal, N et al. EFNS guidelines on the pharmacological treatment of neuropathic pain: 2010 revision. *European Journal of Neurology* 2010; 17: 1113-1123.
6. Dworkin, RH et al. Pharmacologic management of neuropathic pain: evidence-based recommendations. *Pain* 2007 Dec 5; 132 (3):237-51.
7. Argoff, Charles E. et al. Consensus Guidelines: Assessment, Diagnosis, and Treatment of Diabetic Peripheral Neuropathic Pain. *Mayo Clinic Proceedings* April 2006; 81 (4 suppl): S1-S25.
8. Prescriber Information- ZTLido™ Scilex Pharmaceuticals, Inc., San Diego, CA, 92121. Nov. 2018.
9. Prescriber Information- Zilacaine™ Actavis Laboratories UT, Inc. Salt Lake City, UT 84108. June 2018.

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10. Product Information- LidoPure. Actavis Laboratories UT, Inc.Salt Lake City, UT 84108. February 2016.

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**Criteria Change Log**

09/15/2010	Criteria effective date
09/18/2011	Added coverage for neuropathic pain and chronic musculo-skeletal pain
06/15/2012	Combined NC Health Choice and Medicaid coverage criteria
02/26/2019	Added generic lidocaine patch
06/19/2019	Added ZTLido
11/19/2019	Added LidoPure and Zilacaine
11/19/2020	Removed LidoPure
xx/xx/xxxx	Removed Zilacaine Patch and add continuation criteria
xx/xx/xxxx	<p>Separated out criteria for P vs NP agents</p> <p>Added step through preferred lidocaine patch for approval of NP agents</p> <p>Added or beneficiary has a documented clinical reason that these products cannot be tried.</p>