



Original Effective Date: 03/01/2016
 Current Effective Date: 03/07/2024
 Last P&T Approval/Version: 01/31/2024
 Next Review Due By: 01/2025
 Policy Number: C5168-A

Lidocaine Patch

PRODUCTS AFFECTED

Gen7T (lidocaine) patch 3.5% RX, lidocaine 3.5% OTC patch, lidocaine 4% OTC pad/patch, lidocaine 5% RX pad/patch, Lidocan (lidocaine) 5% patch, Lidoderm (lidocaine) 5% patch, Ztlido (lidocaine) 1.8% patch RX

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Post-herpetic neuralgia, Cancer related neuropathy, Diabetic neuropathy

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. POST-HERPETIC NEURALGIA/CANCER-RELATED NEUROPATHY/DIABETIC NEUROPATHY:

1. Documentation of diagnosis of post-herpetic neuralgia or cancer-related neuropathy or diabetic neuropathy
AND

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Drug and Biologic Coverage Criteria

2. (a) Adequate trial and failure of preferred formulary topical dosage form (e.g., OTC 4% patches, cream, or gel).
OR
(b) Documented allergy or clinical contraindication to the formulary agents

CONTINUATION OF THERAPY:

A. POST-HERPETIC NEURALGIA/CANCER-RELATED NEUROPATHY/DIABETIC NEUROPATHY:

1. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity Documentation of no intolerable adverse effects or drug toxicity
AND
2. Documentation of positive clinical response as demonstrated by improvement in pain

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

No requirement

AGE RESTRICTIONS:

1.8% and 5% patch: 18 years of age and older

3.5% and 4% patch: 12 years of age and older

QUANTITY:

90 patches per 30 days

PLACE OF ADMINISTRATION:

The recommendation is that topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Topical.

DRUG CLASS:

Local anesthetic- Topical

FDA-APPROVED USES:

Patch (Lidoderm, ZTlido): Relief of pain associated with postherpetic neuralgia.

Patch (3.5%, OTC 4%): Temporary relief of minor localized pain

COMPENDIAL APPROVED OFF-LABELED USES:

Cancer-related neuropathy, diabetic neuropathy

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

None

Drug and Biologic Coverage Criteria

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses are considered experimental/investigational and therefore will follow Molina's Off- Label policy. Contraindications to lidocaine patch include: Hypersensitivity to lidocaine or any component of the formulation; hypersensitivity to another local anesthetic of the amide type

OTHER SPECIAL CONSIDERATIONS:

OTC 4% patches are available and currently preferred – indicated only for pain relief at this time

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Gen7T PTCH 3.5%
Lidocaine PTCH 3.5%
Lidocaine PTCH 4%
Lidocaine PTCH 5%
Lidocan II PTCH 5%
Lidocan III PTCH 5%
Lidocan PTCH 5%
Lidoderm PTCH 5%
ZTlido PTCH 1.8%

REFERENCES

1. Lidoderm [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc; November 2018.
2. Ztildo [prescribing information]. San Diego, CA: Scilex Pharmaceuticals; April 2021.
3. Aspercreme (lidocaine) patch [prescribing information]. Chattanooga, TN: Chattam Inc; March 2018.
4. Gen7T (lidocaine) patch [prescribing information]. Las Vegas, NV: 7T Pharma LLC; received January 2022.
5. Lidopatch (lidocaine) [prescribing information]. Lake Forest, IL: JAR Laboratories; November 2017.
6. National Comprehensive Cancer Network: Adult Cancer Pain V.1.2018. National Comprehensive Cancer Network. Fort Washington, PA. Available from: https://www.nccn.org/professionals/physician_gls/PDF/pain.pdf
7. Davies PS and Galer BS. Review of lidocaine patch 5% studies in the treatment of postherpetic neuralgia .Drugs. 2004;64(9):937-947.
8. National Comprehensive Cancer Network. 2024. Adult Cancer Pain (Version 2.2023). [online] Available at: <[pain.pdf \(nccn.org\)](https://www.nccn.org/professionals/physician_gls/PDF/pain.pdf)> [Accessed 5 January 2024].

Drug and Biologic Coverage Criteria

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Continuation of Therapy Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Required Medical Information	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file