Pharmacy Medical Necessity Guidelines: Lidocaine 5% Patches

Effective: August 11, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RxUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988
MM: 888.415.9055
PRECERT: 617.972.9409

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

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

COVERAGE GUIDELINES

The plan may authorize coverage of lidocaine 5% patch for members, when the following criteria are met:

1. Documentation of trial and failure or clinical inappropriateness of the over-the-counter lidocaine 4% patches

AND

2. One of the following:
   - Neuropathic pain (e.g., Post Herpetic Neuralgia)
     a. Failure, adverse reaction, or contraindication to gabapentin

   OR

   - Chronic (greater than 3 months) non-neuropathic pain
     b. Documented failure of a trial of at least two of the following drug categories being used for the treatment of non-neuropathic pain: tricyclic antidepressants, SSRI's, SNRI's, anticonvulsants, NSAIDs or COXII and/or opioid analgesics

   Note: A trial consists of at least 30 days of each medication at therapeutic doses.

OR

3. Member is new to plan and pain is currently well controlled on lidocaine 5% patch

LIMITATIONS

- Coverage of lidocaine 5% patch will be limited to 30 patches per 30 days.
- Initial authorization for chronic (greater than 3 months) non-neuropathic pain will be for a period of up to three months. Subsequent authorization for up to one (1) year will require documentation from the provider of sustained clinical effectiveness.
- Brand Lidoderm® patch is not covered; please refer to the Non Covered Drugs with Suggested Alternatives criteria.
- Effective 10.1.18, the over-the-counter lidocaine 4% patches will be covered on Tufts Health Commercial and Tufts Health Direct formularies.

CODES

None

REFERENCES

1. Davis, PS, Galer, BS. Review of lidocaine patch 5% studies in the treatment of postherpetic neuralgia. *Drugs.* 2004; 64(9):937-47.

2. Katz NP, Gammaitoni AR, Davis MW, Dworkin RH, Lidoderm Patch Study Group. Lidocaine patch 5% reduces pain intensity and interference with quality of life in patients with postherpetic neuralgia: an effectiveness trial. *Pain Med.* 2002 Dec; 3(4):324-32.
3. Lidoderm (lidocaine patch 5%) [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc.; 2018 November.

APPROVAL HISTORY

September 8, 2009: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred)
2. July 13, 2010: Removal of, "Tufts Health Plan will not authorize the use of Lidoderm (lidocaine patch 5%) for conditions other than those listed above without clinical justification." And "Documented diagnosis of pain associated with post-herpetic neuralgia." Added: Neuropathic pain: failure, adverse reaction, or contraindication to gabapentin; OR Non-neuropathic pain: failure, adverse reaction, or contraindication to two prescription analgesics (including a narcotic); OR Member is new to plan and pain is currently well controlled on Lidoderm.
3. July 12, 2011: No changes
4. November 15, 2011: Removed the criteria for non-neuropathic pain which required failure, adverse reaction, or contraindication to two prescription analgesics (including a narcotic); and replaced it with Chronic (greater than 3 months) non-neuropathic pain "Documented failure of a trial of at least two of the following drug categories being used for the treatment of non-neuropathic pain: tricyclic antidepressants, SSRI's, SNRI's, anticonvulsants, NSAIDs or COXII and/or opioid analgesics." Added a note: A trial consists of at least 30 days of each medication at therapeutic doses. Added limitation: Initial authorization for non-neuropathic pain will be for a period of up to 3 months. Subsequent authorization for up to one (1) year will require documentation from the provider of sustained clinical effectiveness.
5. October 9, 2012: No changes
6. October 15, 2013: No changes
7. October 7, 2014: No changes
8. October 6, 2015: No changes
9. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
10. September 13, 2016: No changes
11. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
12. September 12, 2017: Effective January 1st, 2018 brand Lidoderm will be moved to not covered. The coverage guidelines and limitation section has been updated to reflect this change.
13. July 11, 2018: Changed the name of MNG to Lidocaine 5% Patches. Also, effective 10.1.18, requiring documentation of trial and failure or clinical inappropriateness of therapy with OTC lidocaine 4% patches.
14. June 11, 2019: Administrative update to the template
15. August 11, 2020: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of

benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.