Pharmacy Medical Necessity Guidelines: tranexamic acid (Lysteda™)

Effective: January 14, 2019

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

Fax Numbers:
RXUM: 617.673.0988

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

OVERVIEW

FDA-APPROVED INDICATIONS
Tranexamic acid (Lysteda™) is an antifibrinolytic indicated for the treatment of cyclic heavy menstrual bleeding.

COVERAGE GUIDELINES
The plan may authorize coverage of tranexamic acid for Members when all the following criteria are met and limitations do not apply:
1. The Member has the diagnosis of heavy menstrual bleeding
   AND
2. The Member tried and failed hormonal therapy, or the provider indicates clinical inappropriateness of hormonal therapy

Hormonal therapy may include:
1. Oral contraceptives
2. Levonorgestrel intrauterine device
3. Progesterone injection

LIMITATIONS
1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria.

CODES
None

REFERENCES

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
- CareLinkSM – 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 RTTogether – A Rhode Island Medicaid Plan

CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
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**APPROVAL HISTORY**
April 14, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. August 12, 2014: No changes
2. August 11, 2015: No changes
3. January 1, 2016: Administrative change to rebranded template.
4. August 9, 2016: Added “Requests for brand-name products, which have AB-rated generics, will be reviewed according to Non-Covered Medications criteria” to the limitations section of the policy.
5. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
7. January 8, 2019: Administrative changes made to template.

**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.

Provider Services