Pharmacy Medical Necessity Guidelines: Endari™ (L-glutamine)

Effective: November 10, 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

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Endari (L-glutamine) is an amino acid indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.

COVERAGE GUIDELINES

Endari (L-glutamine)

The plan may authorize coverage of Endari (L-gluatmine) for Members when all of the following criteria are met:

1. Documented diagnosis of sickle cell anemia

AND

2. Member is at least 5 years of age

AND

3. Prescribed by or in consultation with a hematologist or sickle cell disease specialist

AND

4. Documentation of one of the following:
    a. The Member is stable on hydroxyurea AND experienced at least two painful crises in the last 12 months
    b. Previous trial and failure of, contraindication to, or clinical inappropriateness of treatment with hydroxyurea

LIMITATIONS

None

CODES

None

REFERENCES

1. Brawley OW, Cornelius LJ, Edwards LR et al. National institutes of health consensus development conference statement: hydroxyurea treatment for sickle cell disease. Ann Intern Med. 2008;148(12):932.
2. Endari (L-glutamine) [prescribing information]. Torrance, CA: Emmaus Medical, Inc.; July 2017.
3. Rodger GP. Hydroxyurea use in sickle cell disease. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on October 18, 2018).
4. Yawn BP, Buchanan GR, Afenyi-annan AN, et al. Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members. JAMA. 2014 Sep;312(10):1033-48.

APPROVAL HISTORY

December 12, 2007: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 13, 2018: No changes
2. September 10, 2019: No changes
3. November 12, 2019: Removed Nutrestore (L-glutamine) from the Medical Necessity Guideline because the medication has been discontinued.
4. September 15, 2020: Effective November 10, 2020, changed the name of the Medical Necessity Guideline from "L-glutamine Products" to "Endari (L-glutamine)." Expanded the provider specialty requirement to "Prescribed by or in consultation with a hematologist or sickle cell disease specialist."

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.