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

*Effective: July 1, 2026*

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| 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:<br>☒ Tufts Health RITogether – A Rhode Island Medicaid Plan | | **Fax Numbers:**<br>RXUM: 617.673.0939 | |

**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

The plan may authorize coverage of L-glutamine for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of sickle cell anemia

**AND**

2. Member is 5 years of age or older

**AND**

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

**AND**

4. Documentation of **one (1)** 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

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

## 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.; October 2020.
3. Liem RI, Lanzkron S, Coates TD, et al. American Society of Hematology 2019 guidelines for sickle cell disease: cardiopulmonary and kidney disease. Blood Adv. 2019; 3(23):3867-3897
4. National Institutes of Health, National Heart, Lung, and Blood Institute. (2014). Evidence-based management of sickle cell disease: expert panel report, 2014. Retrieved from https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease.


## APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

- June 13, 2023: No changes
- May 14, 2024: No changes
- June 10, 2025: No changes (eff 6/10/25)
- June 9, 2026: Updated Limitations to add the following language to reflect generic availability of L-glutamine, "Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria" (eff 7/1/26).

## 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