Clinical Policy: L-glutamine (Endari)

Reference Number: IN.CP.PMN.116
Effective Date: 01.01.2022
Last Review Date: 12.21
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

L-glutamine (Endari®) is an amino acid.

FDA Approved Indication(s)

Endari is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Endari is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Member is 5 years of age and older (must meet all)**:**

1. Sickle cell disease, including, but not limited to, homozygous hemoglobin S, sickle hemoglobin C disease, sickle beta^0 thalassemia, and sickle beta+ thalassemia
2. Prescribed by, or in consultation with, a hematologist or other prescriber specialized in the treatment of sickle cell disease
3. One of the following:
    a. Member is currently receiving hydroxyurea therapy
    b. Member has contraindication to or intolerance of hydroxyurea therapy
4. Member has experienced at least 2 sickle cell-related vaso-occlusive crisis events within the previous 12 months while concurrently receiving hydroxyurea therapy (unless member has contraindication to or intolerance of hydroxyurea)
5. Dose does not exceed 30 grams per day based on weight.

Approval duration:
Medicaid – 12 months

B Member is 18 years of age or older AND one of the following:

1. Short bowel syndrome AND all of the following:
    a. Prescribed by, or in consultation with, a gastroenterologist or other prescriber specialized in the treatment of short bowel syndrome
    b. One of the following:

i. Member will be using recombinant human growth hormone concurrently with Lglutamine therapy
ii. Prescriber has provided valid medical rationale against the use of recombinant human growth hormone concurrently with L-glutamine therapy

2. Mucositis following chemotherapy AND the following:
   a. Prescribed by, or in consultation with, an oncologist
3. Prophylaxis of peripheral neuropathy due to oxaliplatin or high-dose paclitaxel use AND the following:
   a. Prescribed by, or in consultation with, an oncologist

II. Continued Therapy

A. Must meet all of the following**:**
1. History of the requested agent within the past 90 days;
2. One of the following:
   a. Member is continuing to utilize required adjunct therapy, if applicable
   b. Medical rationale has been provided for not continuing adjunct therapy

Approval duration:
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
hydroxyurea (Hydrea®, Droxia®)	15 mg/kg PO QD	35 mg/kg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Sickle cell disease	• Weight > 65 kg: 15 g (3 packets) PO BID • Weight 30 to 65 kg: 10 g (2 packets) PO BID • Weight < 30 kg: 5 g (1 packet) PO BID	30 g/day (maximum dose based on weight)

VI. Product Availability
Oral powder: 5 g

VII. References
1. Endari Prescribing Information. Torrance, CA: Emmaus Medical Inc; October 2020. Available at: www.endarirx.com. Accessed July 30, 2021.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, CO: Thomson Healthcare. Updated periodically. Accessed July 30, 2021.
3. 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;312(10):1033-48.
4. Brandow A, Carroll C, Creary S, et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. Blood Advances. 2020;4(12):2656-2701.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created for IN Medicaid Moratorium	12.2021	01.2022