Clinical Policy: L-glutamine (Endari)

Reference Number: ERX.NPA.56
Effective Date: 08.22.17
Last Review Date: 11.17 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 (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Endari is medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. Sickle Cell Disease (must meet all)**:**

1. Diagnosis of sickle cell disease;
2. Age ≥ 5 years;
3. Dose does not exceed:
   a. Weight > 65 kg: 30 g/day (6 packets/day);
   b. Weight 30 kg to 65 kg: 20 g/day (4 packets/day);
   c. Weight < 30 kg: 10 g/day (2 packets/day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Sickle Cell Disease (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
   a. Weight > 65 kg: 30 g/day (6 packets/day);
   b. Weight 30 kg to 65 kg: 20 g/day (4 packets/day);
   c. Weight < 30 kg: 10 g/day (2 packets/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

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

Appendix B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
NutreStore® (l-glutamine)	Adults > 65 kg: 15 g (3 packets) PO twice daily Adults 30 to 65 kg: 10 g (2 packets) PO twice daily Children and adolescents 5 to 17 years: > 65 kg: 15 g (3 packets) PO twice daily 30 to 65 kg: 10 g (2 packets) PO twice daily < 30 kg: 5 g (1 packet) PO twice daily	Adults: 30 grams daily Children: maximum dose based on weight
hydroxyurea (Hydrea®, Droxia®)	15 mg/kg orally once daily	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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Sickle cell disease	Adults > 65 kg: 15 g (3 packets) PO twice daily Adults 30 to 65 kg: 10 g (2 packets) PO twice daily Children and adolescents 5 to 17 years: • > 65 kg: 15 g (3 packets) PO twice daily • 30 to 65 kg: 10 g (2 packets) PO twice daily • < 30 kg: 5 g (1 packet) PO twice daily	Adults: 30 grams daily Children: maximum dose based on weight

VI. Product Availability

Carton of 60 packets: 5 g/packet

VII. References

1. Endari Prescribing Information. Torrance, CA: Emmaus Medical Inc; July 2017. Available at accessdata.fda.gov/drugsatfda_docs/label/2017/208587s000lbl.pdf.
2. NutreStore Prescribing Information. Available at nutrestore.com accessdata.fda.gov/drugsatfda_docs/label/2011/021667s003lbl.pdf
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4. Available at accessdata.fda.gov/drugsatfda_docs/label/2014/202192s008lblPi.pdf
5. Niihara Y. et al. A Phase 3 Study of L-Glutamine Therapy for Sickle Cell Anemia and Sickle ß^0-Thalassemia bloodjournal.org/content/124/21/86?sso-checked=true
6. ClinicalTrials.gov A phase III, prospective, randomized, double-blind, placebo-controlled, parallel-group, multicenter study of l glutamine therapy for sickle cell anemia and sickle ß0-thalassemia
7. nhlbi.nih.gov/sites/www.nhlbi.nih.gov/files/sickle-cell-disease-report%20020816.pdf

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.22.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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