

Clinical Pharmacy Program Guidelines for Endari

Program	Prior Authorization
Medication	L-glutamine powder for solution (Endari)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania CHIP, Rhode Island, South Carolina
Issue Date	11/2017
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

1. Background:

Endari (L-glutamine powder for solution) is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older. The recommended dose is 5 to 15 grams orally twice daily based on body weight.

2. Coverage Criteria:

A. Endari

1. Initial Authorization

a. **Endari** will be approved based on the following criteria:

1) **Both** of the following:

- a) Diagnosis of sickle cell disease
- b) Used to reduce acute complications of sickle cell disease

-AND-

2) **One** of the following:

- a) Patient is using Endari with concurrent hydroxyurea therapy
- b) Patient is unable to take hydroxyurea due to a contraindication or intolerance

-AND-

3) Patient has had 2 or more painful sickle cell crises within the past 12 months

Authorization will be issued for 12 months.

2. Reauthorization

a. **Endari** will be approved based on the following criteria:

- 1) Documentation of positive clinical response to Endari therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

- 1. Endari [package insert]. Torrance, CA: Emmaus Medical, Inc.; October 2020.

Program	Prior Authorization – Endari (L-glutamine powder for solution)
Change Control	
11/2017	New program.
11/2018	Annual review. No changes to criteria.
12/2019	Annual review with no changes.
2/2020	Updated references.
2/2021	Annual review, updated references.