UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2135-9
Program	Prior Authorization/Medical Necessity
Medications	Endari® (L-glutamine Powder for Solution)
P&T Approval Date	11/2017, 2/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023, 2/2024, 2/2025
Effective Date	5/1/2025

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]:

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

- AND –

4) History of failure to non-prescription *L*-glutamine supplementation.

Authorization will be issued for 12 months.

2. **Reauthorization**

1. **Endari** will be approved based on the following criterion:

a. Documentation of positive clinical response to Endari therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- 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.
2. FDA Center For Drug Evaluation and Research Clinical review. Endari. June 7, 2017. 2208587Orig1s000MedR.pdf (fda.gov).

Program	Prior Authorization/Medical Necessity – Endari® (L-glutamine Powder for Solution)
Change Control	
11/2017	New program.
2/2018	Added requirement for *L*-glutamine supplementation.
2/2019	Annual review with no changes.
2/2020	Annual review with no changes.
2/2021	Annual review. Updated references.
2/2022	Annual review with no changes.
2/2023	Annual review. Updated references.
2/2024	Annual review. No changes.
2/2025	Annual review. No changes.