

PRIOR AUTHORIZATION POLICY

POLICY: Sickle Cell Disease – L-glutamine Prior Authorization Policy

- Endari™ (L-glutamine oral powder – Emmaus Medical, generic)

REVIEW DATE: 01/03/2024; selected revision 08/28/2024

OVERVIEW

L-glutamine oral powder, an amino acid, is indicated to **reduce the acute complications of sickle cell disease** in patients ≥ 5 years of age.¹

L-glutamine is an essential amino acid and serves as a precursor of nucleic acids and nucleotides including the pyridine nucleotides (nicotinamide adenine dinucleotide and reduced nicotinamide adenine dinucleotide).^{1,2} These pyridine nucleotides play key roles in the regulation and prevention of oxidative damage in red blood cells and studies have shown that oxidative phenomena may play a significant role in the pathophysiology of sickle cell disease.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of L-glutamine oral powder. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with L-glutamine oral powder as well as the monitoring required for adverse events and long-term efficacy, approval requires L-glutamine oral powder to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required for use of L-glutamine oral powder as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of L-glutamine oral powder is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Sickle Cell Disease [documentation required]**. Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient is ≥ 5 years of age; AND
 - B) The medication is prescribed by or in consultation with a physician who specializes in sickle cell disease (e.g., a hematologist).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of L-glutamine oral powder is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Endari™ oral powder [prescribing information]. Torrance CA: Emmaus Medical; October 2020.
2. Brandow AM, Carroll CP, Creary S, et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. *Blood Adv.* 2020;4:2656-2701.