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5.85.025

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Hematological Agents	**Original Policy Date:**	August 4, 2017
Subject:	Endari	**Page:**	1 of 4

Last Review Date: June 13, 2024

Endari

Description

Endari (L-glutamine oral powder)

Background
Endari is used in the treatment for patients with sickle cell disease to reduce severe complications associated with the blood disorder. Sickle cell disease is an inherited blood disorder in which the red blood cells are abnormally shaped (in a crescent, or "sickle," shape). This restricts the flow in blood vessels and limits oxygen delivery to the body's tissues, leading to severe pain and organ damage (1).

Regulatory Status
FDA-approved indication: Endari is an amino acid indicated to reduce the acute complications of sickle cell disease (SCD) in adult and pediatric patients 5 years of age and older (1).

Two effective disease-modifying therapies for SCD (hydroxyurea and chronic transfusion) are potentially widely available but remain underutilized. These are the only currently proven disease-modifying treatments for people with SCD. Both therapies are used in primary and secondary stroke prevention. Although neither has been shown to prevent all SCD-related organ damage, these treatment modalities can improve the quality of life for individuals with SCD (2).

The safety and effectiveness of Endari have been established in pediatric patients 5 years and older (1).

Related policies
Adakveo, Oxbryta, Siklos

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Endari may be considered **medically necessary** if the conditions indicated below are met.

Endari may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 5 years of age or older

Diagnosis

Patient must have the following:

Sickle Cell Disease (SCD)

AND the following:

1. Inadequate treatment response, intolerance, or contraindication (i.e., renal, cardiovascular, GI) to a 3 month trial of generic hydroxyurea

Prior – Approval *Renewal* Requirements

Age 5 years of age or older

Diagnosis

Patient must have the following:

Sickle Cell Disease (SCD)

AND the following:

1. Reduction in the number of acute complications (i.e., blood transfusions, sickle cell crisis's, hospitalizations) of sickle cell disease since initiating therapy

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Duration 24 months

Rationale

Summary

Endari is used in the treatment for patients with sickle cell disease to reduce severe complications associated with the blood disorder. Sickle cell disease is an inherited blood disorder in which the red blood cells are abnormally shaped (in a crescent, or "sickle," shape). This restricts the flow in blood vessels and limits oxygen delivery to the body's tissues, leading to severe pain and organ damage. Two effective disease-modifying therapies for SCD (hydroxyurea and chronic transfusion) are potentially widely available but remain underutilized. These are the only currently proven disease-modifying treatments for people with SCD (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Endari while maintaining optimal therapeutic outcomes.

References

1. Endari [Package Insert]. Torrance, CA: Emmaus Medical Inc.; October 2020.
2. Gibbons G, Shurin S, et al. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report (EPR), 2014. U.S. Department of Health and Human Services National Institutes of Health.

Policy History

Date	Action
July 2017	Addition to PA
September 2107	Annual review
January 2018	Removal of the requirement of 3 month trial of blood transfusions
March 2018	Annual editorial review Addition of renewal section with reduction in the number of in acute complications of sickle cell disease since initiating therapy and the change from lifetime duration to 12 months for initiation and 24 months for renewal per SME
June 2018	Annual review
September 2019	Annual review
March 2020	Annual review
March 2021	Annual review and reference update
March 2022	Annual review
June 2022	Annual review
March 2023	Annual review. Changed policy number to 5.85.025
June 2023	Annual review
March 2024	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.