Reference number(s)
2208-A

SPECIALTY GUIDELINE MANAGEMENT

ENDARI (L-glutamine oral powder)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Endari is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.

All other indications are considered experimental/investigational and not medically necessary.

II. PRESCRIBER SPECIALITIES

This medication must be prescribed by or in consultation with a hematologist or specialist in sickle cell disease.

III. CRITERIA FOR INITIAL APPROVAL

Sickle cell disease, to reduce the acute complications
Authorization of 12 months may be granted for use in reducing the acute complications of sickle cell disease in members 5 years of age or older when either of the following criteria is met:

A. Member has sickle hemoglobin C (HbSC) or sickle β^+-thalassemia (HbSβ^+) genotype.
B. Member has homozygous hemoglobin S (HbSS) or sickle β^0-thalassemia (HbSβ^0) genotype AND meets any of the following:
    1. Has experienced, at any time in the past, an inadequate response or intolerance to a trial of hydroxyurea.
    2. Has a contraindication to hydroxyurea.
    3. Will be using Endari with concurrent hydroxyurea therapy.

IV. CONTINUATION OF THERAPY

Sickle cell disease, to reduce the acute complications
Authorization of 12 months may be granted for continued treatment when the member has experienced a reduction in acute complications of sickle cell disease (e.g., reduction in the number of painful vaso-occlusive episodes, acute chest syndrome episodes, fever, occurrences of priapism, splenic sequestration) since initiating therapy with Endari.

V. REFERENCES

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

2. Niihara Y, Miller ST, Kanter J, et al. A phase 3 trial of l-glutamine in sickle cell disease. *N Engl J Med*. 2018;379(3):226-235.