



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

L-GLUTAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLUTAMINE (L-GLUTAMINE)	ENDARI		13365	GPI-10 (8280102000)	FDB: BRAND ≠ NUTRESTORE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of sickle cell disease (SCD) and meet **ALL** of the following criteria?

- The medication is prescribed by or given in consultation with a hematologist
- The patient had a trial of or contraindication to hydroxyurea

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient between the ages of 5 to 17 years old?

If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #180 packets per 30 days.**

Approval Text: Renewal requires that the patient has maintained or experienced a reduction in acute complications of sickle-cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, ACS).

If no, continue to #3.

3. Is the patient 18 years of age or older and meets **ONE** of the following criteria?

- The patient had at least 2 sickle cell crises in the past year (A sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac, the occurrence of chest syndrome, priapism, or splenic sequestration)
- The patients is having sickle-cell associated symptoms (e.g., pain or anemia) which are interfering with activities of daily living
- The patients has a history of or has recurrent acute chest syndrome (ACS)

If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #180 packets per 30 days.**

Approval Text: Renewal requires that the patient has maintained or experienced a reduction in acute complications of sickle-cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, ACS).

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **L-GLUTAMINE (ENDARI)** requires the following rule(s) be met for approval:

- A. You have sickle cell disease (type of red blood cell disorder)
- B. You are 5 years of age or older
- C. The medication is prescribed by or given in consultation with a hematologist (blood doctor specialist)
- D. The patient had a trial of or contraindication to hydroxyurea
- E. **If you are 18 years of age or older, approval also requires ONE of the following:**
 - 1. You had at least 2 sickle cell crises in the past year (A sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered given into the vein, narcotic or parenterally administered ketorolac, the occurrence of chest syndrome, priapism (prolonged erection of penis), or splenic sequestration [suppressing of spleen])
 - 2. You are having sickle-cell associated symptoms such as pain or anemia (your blood doesn't have enough healthy red blood cells and you're tired) which are interfering with activities of daily living
 - 3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

- 1. Does the patient have a diagnosis of sickle cell disease **AND** meet the following criterion?
 - The patient has maintained or experienced a reduction in acute complications of sickle-cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, ACS)

If yes, **approve for lifetime by GPID or GPI-10 with a quantity limit of #180 packets per 30 days.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) be met for renewal:

- A. You have sickle cell disease (type of red blood cell disorder)
- B. You have maintained or experienced a reduction in acute complications of sickle-cell disease such as number of sickle cell crises, hospitalizations, acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Endari

REFERENCES

- Endari [Prescribing Information]. Torrance, CA: Emmaus Medical, Inc. October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/20

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P&T Approval: 01/20