

## Clinical Policy: L-glutamine (Endari)

Reference Number: PA.CP.PMN.116

Effective Date: 10.17.18

Last Review Date: 10/30/2019

[Revision Log](#)

### Description

L-glutamine (Endari®) is an amino acid.

### FDA Approved Indication(s)

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

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with PA Health & Wellness® that Endari is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Sickle Cell Disease (must meet all):

1. Diagnosis of sickle cell disease;
2. Failure of hydroxyurea at up to maximally tolerated doses, unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed 30 grams per day based on weight.

**Approval duration:** 12 months

##### B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

#### II. Continued Therapy

##### A. Sickle Cell Disease (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 30 grams per day based on weight.

**Approval duration:** 12 months

##### B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

**Approval duration:** Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
hydroxyurea (Hydrea <sup>®</sup> , Droxia <sup>®</sup> )	15 mg/kg PO QD	35 mg/kg/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

None reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Sickle cell disease	Weight > 65 kg: 15 g (3 packets) PO BID	30 g/day (maximum dose based on weight)
	Weight 30 to 65 kg: 10 g (2 packets) PO BID	
	Weight < 30 kg: 5 g (1 packet) PO BID	

**VI. Product Availability**

Oral powder: 5 g

**VII. References**

1. Endari Prescribing Information. Torrance, CA: Emmaus Medical Inc; July 2017. Available at: [accessdata.fda.gov/drugsatfda\\_docs/label/2017/208587s000lbl.pdf](https://accessdata.fda.gov/drugsatfda_docs/label/2017/208587s000lbl.pdf). Accessed August 14, 2018.

2. Droxia Prescribing Information. Princeton, NJ: Bristol-Myers Squibb Company Available at: [https://packageinserts.bms.com/pi/pi\\_droxia.pdf](https://packageinserts.bms.com/pi/pi_droxia.pdf). Accessed August 14, 2018.
3. Yawn BP, Buchanan GR, Afenyi-Annan AN, et al. Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members. JAMA 2014;312(10):1033-48.
4. U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute. The Management of Sickle Cell Disease (NIH Publication No. 02-2117). (2002). Retrieved from [https://www.nhlbi.nih.gov/files/docs/guidelines/sc\\_mngt.pdf](https://www.nhlbi.nih.gov/files/docs/guidelines/sc_mngt.pdf).

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10/18	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	

**Note:**

**For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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