Prior Authorization Review Panel

Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2020**
Policy Number: PA.CP.PMN.116	**Effective Date: 01/2020** **Revision Date: 10/2020**
Policy Name: L-glutamine (Endari)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

References reviewed and updated

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

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. Age ≥ 5 years;
3. Failure of hydroxyurea at up to maximally tolerated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. 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®, Droxia®)	15 mg/kg PO QD	35 mg/kg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) 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 Weight 30 to 65 kg: 10 g (2 packets) PO BID Weight < 30 kg: 5 g (1 packet) PO BID	30 g/day (maximum dose based on weight)

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. Accessed August 10, 2020.

2. Droxia Prescribing Information. Princeton, NJ: Bristol-Myers Squibb Company; December 2019. Available at: https://packageinserts.bms.com/pi/pi_droxia.pdf. Accessed August 11, 2020.
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.

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	
4Q 2020 annual review: References reviewed and updated	08/20	11/20