RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	l-glutamine
Policy Number:	RxA.366
Drug(s) Applied:	Endari®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

L-glutamine (Endari®) is an amino acid. It is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
L-glutamine (Endari®)	Sickle cell disease	Weight > 65 kg: 15 g (3 packets) PO twice daily Weight 30 to 65 kg: 10 g (2 packets) PO twice daily Weight < 30 kg: 5 g (1 packet) PO twice daily	30 g/day (maximum dose based on weight)

Dosage Forms

- Oral powder: 5 g

Clinical Policy

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

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
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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	Maximum Dose
Hydroxyurea (Hydrea®, Droxia®)	15 mg/kg PO once daily	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

APPENDIX D: General Information
• Not Applicable

References

1. Endari Prescribing Information. Torrance, CA: Emmaus Medical Inc; November 2019. Available at: www.endarirx.com. Accessed July 12, 2020.
2. Droxia Prescribing Information. Princeton, NJ: Bristol-Myers Squibb Company Available at: https://packageinserts.bms.com/pi/pi_droxia.pdf. Accessed July 12, 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.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Continued therapy criteria II.A.1	07/12/2020	09/14/2020

was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 3. Age symbols and approval duration was updated in initial as well as in continued therapy approval. 4. QD was updated to "once daily" in document. 5. References were updated.		