Endari (L-glutamine)

Override(s)	Approval Duration
Prior Authorization	Initial requests: 1 year Continuation requests: 1 year

Medications
Endari (L-glutamine)

APPROVAL CRITERIA

Initial requests for Endari (L-glutamine) may be approved if the following criteria are met:

I. Individual is 5 years of age or older; **AND**
II. Documentation is provided that individual has a diagnosis of sickle cell anemia with the following confirmed:
   A. Diagnoses of HbSS or HbS/β^0- thalassemia; **AND**
   B. Documentation is provided that individual has had at least two episodes of sickle cell crises (SCC) in the last 12 months.

Continuation requests for Endari (L-glutamine) may be approved if the following criterion is met:

I. Documentation is provided that individual experienced a reduction in acute complications of sickle cell disease (e.g. reduction in the number of vaso-occlusive episodes, acute chest syndrome episodes) since initiating Endari.

Key References:

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2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed on: April 4, 2022
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Endari [package insert] Torrance, CA. Emmaus Medical, Inc.; 2017.
6. European Sickle Cell Disease Cohort-Hydroxyurea (ESCORT-HU) (2018). Retrieved from https://clinicaltrials.gov/ct2/show/NCT02516579 (Identification No. NCT02516579).
7. Klings ES, Machado RF, Barst RJ, et al; American Thoracic Society Ad Hoc Committee on Pulmonary Hypertension of Sickle Cell Disease. An official American Thoracic Society clinical practice guideline: diagnosis, risk stratification, and management of pulmonary hypertension of sickle cell disease. *Am J Respir Crit Care Med.* 2014;189:727-40. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3983842/pdf/rccm.201401-0065ST.pdf. Accessed April 7, 2022.
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.

9. Montalembert M, Galacteros F, Ribeil JA, et al. Implementation of a European Cohort to Follow Sickle Cell Children and Adults treated with Hydrooxycarbamide. Blood 2014; 124: 564. Available at http://www.bloodjournal.org/content/124/21/564?sso-checked=true . Accessed on March 29, 2021.
10. National Heart, Lung, and Blood Institute. Evidence-based management of sickle cell disease: Expert Panel Report, 2014. Available at: https://www.nhlbi.nih.gov/health-topics/all-publications-and-resources/evidence-based-management-sickle-cell-disease-expert-0 . Accessed April 4, 2022.
11. Niihara Y, Koh HA, Tran L, et al. A Phase 3 Study of L-Glutamine Therapy for Sickle Cell Anemia and Sickle ß^0-Thalassemia. *Blood*. 2014;124:86. (poster abstract) available at http://www.bloodjournal.org/content/124/21/86?sso-checked=true. Accessed on April 4, 2022.