Oxbryta® (voxelotor)
(Oral)

Document Number: IC-P0516

Last Review Date: 02/01/2024
Date of Origin: 01/03/2020
Dates Reviewed: 01/2020, 01/2021, 01/2022, 01/2023, 02/2024

I. Length of Authorization

Initial coverage will be provided for 6 months and may be renewed every 12 months thereafter.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Oxbryta 300 mg tablets: 5 tablets daily
- Oxbryta 500 mg tablets: 3 tablets daily
- Oxbryta 300 mg tablets for oral suspension: 5 tablets daily

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1500 mg daily

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- The patient has a diagnosis of sickle cell disease; **AND**
- If the patient has an FDA approved indication, then ONE of the following:
  - The patient's age is within FDA labeling for the requested indication for the requested agent; **OR**
  - The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication; **AND**
- ONE of the following:
  - The patient has tried and had an inadequate response after at least 6 months of therapy with maximally tolerated hydroxyurea; **OR**
  - The patient has an intolerance or hypersensitivity to hydroxyurea; **OR**
  - The patient has an FDA labeled contraindication to hydroxyurea; **AND**
- ONE of the following:

- The patient's baseline (before treatment with the requested agent) hemoglobin is greater than or equal to 5.5 and less than or equal to 10.5 g/dL; **OR**
- The patient's baseline (before treatment with the requested agent) hemoglobin is below the lab reference range for the patient's age and gender; **AND**

- ONE of the following:
  - The patient will NOT be using the requested agent in combination with Adakveo (crizanlizumab-tmca) OR Endari (L-glutamine) for the requested indication; **OR**
  - Information has been provided supporting the use of the requested agent in combination with Adakveo (crizanlizumab-tmca) or Endari (L-glutamine) for the requested indication; **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- The patient has been previously approved for the requested agent through the plan's Prior Authorization process; **AND**
- The patient has had clinical benefit with the requested agent indicated by one of the following:
  - The patient had an increase in hemoglobin level of greater than 1 g/dL from baseline (before treatment with the requested agent); **OR**
  - The patient has a hemoglobin level within the normal range for age and gender; **OR**
  - Information has been provided supporting continuation with the requested agent (medical records required); **AND**
- ONE of the following:
  - The patient will NOT be using the requested agent in combination with Adakveo (crizanlizumab-tmca) OR Endari (L-glutamine) for the requested indication; **OR**
  - Information supporting the use of the requested agent in combination with Adakveo (crizanlizumab-tmca) or Endari (L-glutamine) for the requested indication; **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent

V. Dosage/Administration

Indication	Dose
Sickle Cell Disease	**Pediatric Patients 4 years to <12 years of age** • ≥40 kg: 1,500 mg orally once daily • 20 kg to <40 kg: 900 mg orally once daily • 10 kg to <20 kg: 600 mg orally once daily ***NOTE:** Select the appropriate product (Oxbryta tablets or Oxbryta tablets for oral suspension) based on patient's ability to swallow tablets and patient*

	weight. Oxbryta oral tablets are available as 300 mg or 500 mg and Oxbryta tablets for oral suspension are available as 300mg. **Adults and Pediatric Patients ≥12 years of age** • 1,500 mg orally once daily

VI. Billing Code/Availability Information

HCPCS:

- J8499 – Prescription drug, oral, non chemotherapeutic, nos

NDC:

- Oxbryta 300 mg tablets: 72786-0102-xx
- Oxbryta 500 mg tablets: 72786-0101-xx
- Oxbryta 300 mg tablets for oral suspension: 72786-0111-xx

VII. References

1. Oxbryta [package insert]. San Francisco, CA; Global Blood Therapeutics, Inc., October 2022. Accessed November 2022.
2. Bender MA, Carlberg K. Sickle Cell Disease. 2003 Sep 15 [Updated 2022 Nov 17]. In: Adam MP, Everman DB, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1377/.
3. Vichinsky E, Hoppe CC, Ataga KI, et al; HOPE Trial Investigators. A Phase 3 Randomized Trial of Voxelotor in Sickle Cell Disease. N Engl J Med. 2019 Aug 8;381(6):509-519. Doi: 10.1056/NEJMoa1903212. Epub 2019 Jun 14.
4. 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 Sep 10;312(10):1033-48.
5. Estepp JH, Kalpatthi R, Woods G, et al. Safety and Efficacy of Voxelotor in Pediatric Patients With Sickle Cell Disease Aged 4-11 Years: Results From the Phase 2a HOPE-KIDS 1 Study. Presentation given during European Hematology Association Congress 2021.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D57.01	Hb-SS disease with acute chest syndrome
D57.02	Hb-SS disease with splenic sequestration
D57.03	Hb-SS disease with cerebral vascular involvement
D57.09	Hb-SS disease with crisis with other specified complication
D57.1	Sickle-cell disease without crisis
D57.20	Sickle-cell/Hb-C disease without crisis

D57.211	Sickle-cell/Hb-C disease with acute chest syndrome
D57.212	Sickle-cell/Hb-C disease with splenic sequestration
D57.213	Sickle-cell/Hb-C disease with cerebral vascular involvement
D57.218	Sickle-cell/Hb-C disease with crisis with other specified complication
D57.3	Sickle-cell trait
D57.411	Sickle-cell thalassemia with acute chest syndrome
D57.412	Sickle-cell thalassemia with splenic sequestration
D57.418	Sickle-cell thalassemia, unspecified, with crisis with other specified complication
D57.42	Sickle-cell thalassemia beta zero without crisis
D57.431	Sickle-cell thalassemia beta zero with acute chest syndrome
D57.432	Sickle-cell thalassemia beta zero with splenic sequestration
D57.433	Sickle-cell thalassemia beta zero with cerebral vascular involvement
D57.438	Sickle-cell thalassemia beta zero with crisis with other specified complication
D57.439	Sickle-cell thalassemia beta zero with crisis, unspecified
D57.44	Sickle-cell thalassemia beta plus without crisis
D57.451	Sickle-cell thalassemia beta plus with acute chest syndrome
D57.452	Sickle-cell thalassemia beta plus with splenic sequestration
D57.453	Sickle-cell thalassemia beta plus with cerebral vascular involvement
D57.458	Sickle-cell thalassemia beta plus with crisis with other specified complication
D57.459	Sickle-cell thalassemia beta plus with crisis, unspecified
D57.80	Other sickle-cell disorders without crisis
D57.811	Other sickle-cell disorders with acute chest syndrome
D57.812	Other sickle-cell disorders with splenic sequestration
D57.813	Other sickle-cell disorders with cerebral vascular involvement
D57.818	Other sickle-cell disorders with crisis with other specified complication

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC