Oxbryta (voxelotor)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initiation: 1 year Continuation: 1 year

Medications	Quantity Limit
Oxbryta (voxelotor) 300 mg tablets for oral suspension	5 tablets per day
Oxbryta (voxelotor) 300 or 500 mg tablets	3 tablets per day

If individual is using Oxbryta (voxelotor) in combination with strong or moderate CYP3A4 inducers (e.g. rifampin) dose may be increased to up to 2,500 mg per day.

APPROVAL CRITERIA

Initial requests for Oxbryta (voxelotor) may be approved if the following criteria are met:

I. Individual is 4 years of age or older; **AND**
II. Individual has a diagnosis of sickle cell disease; **AND**
III. Documentation is provided that individual had at least one episode of sickle cell related pain crises (vaso-occlusive crises), in the past 12 months; **AND**
IV. If individual continues using in combination with hydroxyurea, the hydroxyurea dose must be stable for at least 3 months.

Continuation requests for Oxbryta (voxelotor) 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, hemoglobin improvement) since initiating Oxbryta.

Requests for Oxbryta (voxelotor) may not be approved when the above criteria are not met and for the following:

I. Individual is on a chronic transfusion program; **OR**
II. Individual is using in combination with crizanlizumab (Adakveo) (Absiola 2022).

Key References:

1. Abisola Baruwa Etti, Chia-ling Kuo, Lucas Da Cunha Godoy, Biree Andemariam; Real-World Outcomes in Adult Sickle Cell Disease Patients Treated with Crizanlizumab, Voxelotor or Both. *Blood* 2022; 140 (Supplement 1): 8292–8293. doi: https://doi.org/10.1182/blood-2022-170808
2. Brown C, Hoppe C, Inati A, et al. Efficacy and Safety of 1500 mg Voxelotor in a Phase 2a Study (GBT440-007) in Adolescents with Sickle Cell Disease. Blood:132(Suppl 1):509..
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: http://www.clinicalpharmacology.com. Updated periodically.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
7. Vichinsky E, Hoppe CC, Ataga KI, et al. A phase 3 randomized trial of Voxelotor in sickle cell disease. *N Engl J Med*. 2019;381(6):509-519.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.