Oxbryta (voxelotor)

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

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

*If individual is using Oxbryta (voxelotor) 300 mg tablets or tablets for oral suspension in combination with strong or moderate CYP3A4 inducers (e.g. rifampin) dose may be increased to up to 2,400 mg per day.

**If individual is using Oxbryta (voxelotor) 500 mg tablets 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; **AND**
V. Individual is not using in combination with crizanlizumab (Adakveo).

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.

Key References:

1. 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. Accessed April 7, 2022.
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: April 7, 2022
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. 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.