

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Oxbryta (voxelotor)

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

Medications	Quantity Limit
Oxbryta (voxelotor) 500 mg	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

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

- I. Individual is 12 years of age or older; **AND**
- II. Individual has a diagnosis of sickle cell disease; **AND**
- III. Prior to initiation of Oxbryta therapy, 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).

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 has severe renal dysfunction defined as $<30 \text{ mL/min/1.73 m}^2$ or on chronic dialysis.

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 2, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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 2, 2020.

CRX-ALL-0572-20

PAGE 1 of 2 07/23/2020
New Program Date 12/20/2019

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; 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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.