



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 21, 2020 October 13, 2021, December 22, 2021

OXBRYTA™ (voxelotor)

LENGTH OF AUTHORIZATION: Up to 6 months

INITIAL REVIEW CRITERIA:

- Patient must have a diagnosis of sickle cell disease.
- Prescribed by or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease.

Patients 12 years of age or older:

- Must have experienced at least one vaso-occlusive crisis within the past 12 months (documentation required).
- Must have a documented baseline hemoglobin range is ≥ 5.5 g/dL and ≤ 10.5 g/dL.

Patient 4 to < 12 years of age:

- Must not have experienced a vaso-occlusive crisis within 14 days of treatment (documentation required).
- Must have a documented baseline hemoglobin ≤ 10.5 g/dL.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of positive clinical response from one of the following (1) increase in hemoglobin by ≥ 1 g/dL from baseline, (2) reduction in the number of sickle cell-related vaso-occlusive crises, (3) reduction in percent reticulocyte count from baseline **OR** (4) reduction in indirect bilirubin count from baseline.
- Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines.

DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as 500 mg tablets and 300 mg tablets for oral suspension.