Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 21, 2020 October 13, 2021, December 22, 2021, June 13, 2023, July 18, 2023, January 24, 2024, July 1, 2024, August 14, 2024

OXBRYTA® (voxelotor)

LENGTH OF AUTHORIZATION: 1 year

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 4 to < 12 years of age:

- Must have a documented baseline hemoglobin ≤ 10.5 g/dL.

Patients 12 years of age or older:

- Must have a documented baseline hemoglobin range of ≥ 5.5 g/dL and ≤ 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 ≥ 1g/dL from baseline, (2) reduction in percent reticulocyte count from baseline **OR** (3) reduction in indirect bilirubin count from baseline (clinical records and lab documentation required within the last 90 days).
- 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 300mg and 500 mg tablets and 300 mg tablets for oral suspension.