CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Oxbryta (voxelotor)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Oxbryta, approved by the FDA in 2019, is a hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 4 years of age and older. It binds to HbS and exhibits preferential partitioning to red blood cells (RBCs). By increasing the affinity of Hb for oxygen, it demonstrates inhibition of HbS polymerization. Nonclinical studies suggest that Oxbryta may inhibit RBC sickling, improve RBC deformability, and reduce whole blood viscosity. This indication is approved under accelerated approval based on increase in hemoglobin (Hb). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
Sickle cell disease is caused by an inherited mutation in the beta globin gene, resulting in abnormal hemoglobin called sickle hemoglobin (HbS). Red blood cells become rigid, undergo premature hemolysis leading to anemia, and become unable to transport oxygen to critical organs. Patients experience severe pain from vaso-occlusive crises. First line therapy for sickle cell patients is hydroxyurea.

Oxbryta (voxelotor) will be considered for coverage when the following criteria are met:

Sickle Cell Disease (SCD)

For **initial** authorization:
1. Member must be 4 years of age or older; AND
2. Medication is prescribed by or in consultation with a hematologist; AND
3. Member has a confirmed diagnosis of sickle cell disease with at least **ONE** vaso-occlusive crisis within the past 12 months; AND
4. Member has a baseline hemoglobin level between 5.5-10.5 g/dL documented in chart notes; AND
5. Member has had a 6-month trial of hydroxyurea and the trial was ineffective or not tolerated; AND
6. Medication will **NOT** be used concurrently with Adakveo (crizanlizumab-tmca) therapy.
7. **Dosage allowed/Quantity limit:** Quantity Limit: 90 tablets per 30 days.
   a) 12 years and older: 1,500 mg by mouth daily.
   b) 4 years of age to less than 12 years of age: see table below.

Body Weight	Recommended Dose (Once Daily)
40 kg or greater	1,500 mg
20 kg to less than 40 kg	900 mg
10 kg to less than 20 kg	600 mg

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided showing an increase in hemoglobin by at least ≥1 g/dL from baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Oxbryta (voxelotor) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/30/2020	New policy for Oxbryta created.
02/21/2022	Transferred to new template. Removed must meet initial criteria from reauth. Updated age limit to 4 years. Updated dosing. Added references.
01/23/2024	Increased hydroxyurea trial from 3 months to 6 months; removed absence chronic blood transfusions requirement; updated, added, removed references; removed prescriber specialty being physician who has experience in treating sickle cell disease.

References:

1. Oxbryta [Package Insert]. South San Francisco, CA: Global Blood Therapeutics, Inc.; 2023.
2. Vichinsky E, Hoppe CC, Ataga KI, et al; HOPE Trial Investigators. A phase 3 randomized trial of voxelotor in sickle cell disease. *N Engl Med.* 2019;381(6):509-519.
3. Bradt P, Spackman E, Synnott PG, Chapman R, Beinfeld M, Rind DM, Pearson SD. Crizanlizumab, Voxelotor, and L-Glutamine for Sickle Cell Disease: Effectiveness and Value. Institute for Clinical and Economic Review, January 23, 2020. https://icer-review.org/material/sickle-cell-disease-draft-evidence-report/.
4. 5. Voskaridou E, Christoulas D, Bilalis A, et al. The effect of prolonged administration of hydroxyurea on morbidity and mortality in adult patients with sickle cell syndromes: results of a 17-year, single-center trial (LaSHS). Blood. 2010;115(12):2354-2363.
5. Yawn BP, Buchanan GR, Afenyi-Annan AN, et al. Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members [published correction appears in JAMA. 2014 Nov 12;312(18):1932] [published correction appears in JAMA. 2015 Feb 17;313(7):729]. *JAMA*. 2014;312(10):1033-1048. doi:10.1001/jama.2014.10517

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