CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Oxbryta (voxelotor)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Oxbryta is indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 4 years of age and older. 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 is a hemoglobin S (HbS) polymerization inhibitor that 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.

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

Sickle Cell Disease

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 or a physician who has experience in treating sickle cell disease; 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 tried hydroxyurea for at least 3 months and the trial was ineffective or not tolerated; AND
6. Member will NOT be receiving chronic blood transfusion therapy; AND
7. Medication will NOT be used concurrently with Adakveo (crizanlizumab-tmca) therapy.
8. **Dosage allowed/Quantity limit:**
   Age 12 years and older: 1,500 mg by mouth daily (90 tablets per 30 days)
   Age 4 to less than 12 years: Tablets or tablets for oral suspension; weight based:

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 ≥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.

References:

1. Oxbryta [Package Insert]. South San Francisco, CA: Global Blood Therapeutics, Inc.; December 2021.
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. Niihara Y, Miller ST, Kanter J, et al. A phase 3 trial of L-glutamine in sickle cell disease. N Engl Med. 2018;379:226-235.
4. 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/
5. IPD Analytics. Accessed February 21, 2022.
6. Yawn BP, John-Sowah J. Management of Sickle Cell Disease: Recommendations from the 2014 Expert Panel Report. *Am Fam Physician*. 2015;92(12):1069-1076.

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