

Reference number(s) 3426-A

# Specialty Guideline Management Oxbryta

## **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Oxbryta	voxelotor

## **Indications**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

## FDA-approved Indication

Oxbryta is indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 4 years of age and older.

All other indications are considered experimental/investigational and not medically necessary.

## **Prescriber Specialties**

This medication must be prescribed by or in consultation with a hematologist or specialist in sickle cell disease.

# **Coverage Criteria**

Oxbryta SGM 3426-A P2024\_R.docx

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#### Sickle cell disease (SCD)

Authorization of 6 months may be granted for treatment of sickle cell disease in members 4 years of age or older with a pretreatment hemoglobin level of 10.5 g/dL or less, when either of the following criteria is met:

- Member has sickle hemoglobin C (HbSC), sickle  $\beta^+$ -thalassemia (HbS $\beta^+$ ), or other genotypic variants of sickle cell disease (e.g., HbS-O Arab, HbS-Lepore).
- Member has homozygous hemoglobin S (HbSS) or sickle  $\beta^0$ -thalassemia (HbS $\beta^0$ ) genotype AND meets any of the following:
  - Has experienced, at any time in the past, an inadequate response or intolerance to a trial of hydroxyurea
  - Has a contraindication to hydroxyurea
  - Will be using Oxbryta with concurrent hydroxyurea therapy

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion.

# **Continuation of Therapy**

## Sickle cell disease (SCD)

Authorization of 12 months may be granted for continued treatment in members experiencing benefit from therapy as demonstrated by increased hemoglobin levels or maintenance of increased hemoglobin levels since starting treatment.

## References

- 1. Oxbryta [package insert]. South San Francisco, CA: Global Blood Therapeutics, Inc.; August 2023.
- 2. Vichinsky E, Hoppe CC, Ataga KI, et al. A phase 3 randomized trial of voxelotor in sickle cell disease. N Engl J Med. 2019 Aug 8;381(6):509-519.