SPECIALTY GUIDELINE MANAGEMENT

OXBRYTA (voxelotor)

POLICY

I. 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.

II. CRITERIA FOR INITIAL APPROVAL

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.

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

III. CONTINUATION OF THERAPY

Sickle cell disease (SCD)

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

IV. REFERENCES

- 1. Oxbryta [package insert]. South San Francisco, CA: Global Blood Therapeutics, Inc.; December 2021.
- 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.

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