PRIOR AUTHORIZATION POLICY

POLICY: Sickle Cell Disease – Oxbryta Prior Authorization Policy
- Oxbryta® (voxelotor tablets, tablets for oral suspension – Global Blood Therapeutics)

REVIEW DATE: 12/07/2022

OVERVIEW

Oxbryta, a hemoglobin S (or sickle hemoglobin) polymerization inhibitor, is indicated for the treatment of **sickle cell disease** in patients ≥ 4 years of age.[1]

Guidelines

The American Society of Hematology guidelines for sickle cell disease: management of acute and chronic pain associated with sickle cell disease (2020) does not address the use of Oxbryta.[2] The National Institutes of Health – National Heart, Lung, and Blood Institute issued the Evidence-Based Management of Sickle Cell Disease, Expert Panel Report in 2014.[3] These guidelines were published prior to the approval of Oxbryta. Hydroxyurea has been shown to reduce the frequency of painful episodes, the incidence of acute coronary syndrome events, and the need for transfusions and hospitalizations.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Oxbryta. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Oxbryta as well as the monitoring required for adverse events and long-term efficacy, approval requires Oxbryta to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Oxbryta is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Sickle Cell Disease.** Approve for 1 year if the patient meets ONE of the following criteria (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL of the following criteria (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 4 years of age; AND
     - **ii.** If the patient is ≥ 12 years of age, patient has had at least one sickle cell-related crisis in the previous 12-month period; AND
     - **iii.** Patient's baseline hemoglobin level was ≤ 10.5 g/dL (before initiating Oxbryta therapy); AND
     - **iv.** Patient meets one of the following criteria (a, b, or c):
       - **a)** Patient is currently receiving a hydroxyurea product; OR
       - **b)** According to the prescriber, patient has tried a hydroxyurea product and has experienced inadequate efficacy or significant intolerance; OR
       - **c)** According to the prescriber, patient is not a candidate for hydroxyurea therapy; AND
         Note: Examples of patients who are not candidates for hydroxyurea therapy include patients who are pregnant or who are planning to become pregnant and patients with an immunosuppressive condition (such as cancer).

v. The medication is prescribed by or in consultation with a physician who specializes in sickle cell disease (e.g., a hematologist).

B) Patient is Currently Receiving Oxbryta. Approve for 1 year if the patient meets ALL of the following criteria (i, ii, and iii):

i. Patient is ≥ 4 years of age; AND

ii. According to the prescriber, patient is receiving clinical benefit from Oxbryta therapy; AND
Note: Examples of clinical benefit include reduction in the number of vaso-occlusive crises/sickle cell-related crises; delay in time to sickle cell-related crises; and reduction in the number of days in the hospital.

iii. The medication is prescribed by or in consultation with a physician who specializes in sickle cell disease (e.g., a hematologist).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Oxbryta is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Oxbryta™ tablets and tablets for oral suspension [prescribing information]. San Francisco, CA: Global Blood Therapeutics; October 2022.
2. Brandow AM, Carroll CP, Creary S, et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. *Blood Adv*. 2020;4:2656-2701
3. The National Institutes of Health – National Heart, Lung, and Blood Institute Evidence-Based Management of Sickle Cell Disease, Expert Panel Report 2014. Available at: https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Accessed on November 28, 2022.