MEDICAL MUTUAL®

Drug Policy

Policy:	Oxbryta (voxelotor)	Annual Review Date: 01/16/2025 Last Revised Date: 01/16/2025

OVERVIEW

Oxbryta is a hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease in adults and pediatric patients 12 years of age and older. Non-clinical studies suggest that voxelotor may inhibit red blood cell (RBC) sickling, improve RBC deformability, and reduce whole blood viscosity.

POLICY STATEMENT

This policy involves the use of Oxbryta. Prior authorization is recommended for pharmacy benefit coverage of Oxbryta. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Oxbryta be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Sickle Cell Disease, initial therapy**
   Criteria. *Patient must meet the following criteria*
   - **A.** The patient is 4 years of age or older; AND
   - **B.** The patient has a history of at least one vaso-occlusive crisis (VOC) in the prior 6 months; AND
   - **C.** The patient has tried and failed hydroxyurea and L-glutamine

2. **Sickle Cell Disease, continuation of therapy**
   Criteria. *Patient must meet the following criteria*
   - **A.** The patient is 4 years of age or older; AND
   - **B.** The patient has had an appropriate hemoglobin response to use of Oxbryta, as determined by the prescriber

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Oxbryta has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concomitant use with Adakveo.** There are no data available to support the use of Oxbryta in combination with Adakveo.

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Oxbryta [prescribing information]. Global Blood Therapuetics Inc; South San Francisco, CA. Dec 2021.
2. Voxelotor. In: DRUGDEX [online database]. Truven Health Analytica; Greenwood Village, CO. Last updated 9 December 2019. Accessed on 16 December 2019.