WELL SENSE HEALTH PLAN

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Pharmacy Policy

Oxbryta

Policy Number: 9.612
Revision Number: R0
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☒ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☐ MassHealth - MCO ☐ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Oxbryta (voxelotor)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	• Concomitant chronic, prophylactic blood transfusion therapy • Concomitant use with Adakveo (crizanlizumab-tmca) • HgB ≥ 10.5 g/dl
Required Medical Information	1. Diagnosis of sickle cell disease; ***AND*** 2. Documentation of HgB level ≤7 g/dL within the last 60 days; ***AND*** 3. Documentation of one (1) or more sickle cell-related vaso-occlusive crises within the previous 12 months; ***AND*** 4. Current hydroxyurea therapy for at least 6 months with stable dose for at least 3

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	months OR documentation of previous treatment failure, intolerance, or contraindication to hydroxyurea therapy at least 6 months with stable dose for at least 3 months.
Age Restriction	12 years of age or older
Prescriber Restriction	Prescribed by or in consultation with a hematologist or sickle cell disease specialist.
Coverage Duration	Initial: 6 weeks Reauthorization: 12 months
Quantity Limit	90 tablets per 30 days
Other criteria	Reauthorization: Documentation of the following: 1. Positive clinical response to Oxbryta as demonstrated by an Increase in HgB level from baseline by at least 1g/dL; ***AND*** 2. Patient did not receive an acute blood transfusion during initial 6 week authorization period or for annual reauthorizations, patient has not experienced an increase in transfusions

Applicable Coding:

Clinical Background Information and References

1. Oxbryta (voxelotor) [package insert]. South San Francisco, CA: Global Blood Therapeutics, Inc.; November 2019.
2. Vichinsky E et. al. Up to Date: Overview of Clinical Manifestations of sickle Cell Disease. Post, TW (Ed), UpToDate, Waltham, MA, 2020.
3. Vichinsky E, Hoppe C, Ataga K, et al. A phase 3 randomized trial of voxelotor in sickle cell disease. N Engl J Med. 2019; 381:509-19.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.200 Oxbryta Policy retired, new policy created.	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.