JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS123
		Effective Date	05/15/2020
		Review Date	07/19/2023
	Subject **Oxbryta**	*Revision Date*	07/19/2023
		Page	1 of 2

This document applies to the following Participating Organizations:

Priority Partners

Keywords: Oxbryta

Table of Contents		Page Number
I.	**POLICY**	**1**
II.	**POLICY CRITERIA**	**1**
	A. Oxbryta	**1**
III.	**AUTHORIZATION PERIOD/LIMITATIONS**	**1**
IV.	**EXCLUSIONS**	**2**
V.	**REFERENCES**	**2**
VI.	**APPROVALS**	**2**

I. POLICY

Oxbryta (voxelotor) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Oxbryta** may be approved for patients meeting ALL the following:
   1. Patient is 4 years of age or older
   2. Documented diagnosis of Sickle Cell Disease
   3. Documentation has been submitted showing that the patient has experienced at least one sickle cell-related vaso-occlusive crisis within the past 12 months
   4. Patient has a baseline hemoglobin that is at or between 5.5 g/dL and 10.5 g/dL
   5. Documentation has been submitted showing baseline indirect (unconjugated) bilirubin and percent reticulocyte count
   6. Documentation has been submitted showing one of the following:
      a. Patient has had inadequate response to an optimally dosed hydroxyurea regimen (lack of increase in hemoglobin). An adequate trial would consist of a stable dose of hydroxyurea for at least 3 months, unless the use of hydroxyurea is contraindicated, or clinically significant adverse reactions occur.
      b. A clinical assessment documenting that hydroxyurea will not improve the patient's hemoglobin to a clinically acceptable level.
   7. The prescriber is, or has consulted with, a hematologist or sickle cell disease specialist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy
B. Approval for continuation of therapy may be extended in 12-month intervals with evidence of patient's tolerance, and clinical improvement as demonstrated by documentation of at least one of the following:

1. Increase in hemoglobin by greater than 1 g/dL from baseline level
2. Decrease in indirect bilirubin from baseline
3. Decrease in percent reticulocyte count from baseline

IV. EXCLUSIONS

A. Oxbryta will not be approved for the following:
   1. Patients that are less than 4 years of age
   2. Patients with severe renal dysfunction, defined as less than defined as <30 mL/min/1.73 m^2 or on chronic dialysis
   3. Patients receiving concurrent chronic prophylactic blood transfusion therapy
   4. Concurrent use with Adakveo (crizanlizumab-tmca)
   5. Dosing schedules greater than 1,500 mg per day
   6. Any indications or other uses that are not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Oxbryta [Prescribing Information]. Global Blood Therapeutics Inc: South San Francisco, CA; October 2022

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
05/14/2020	Policy Creation
12/08/2021	Updated Exclusions section regarding physician samples
07/19/2023	Clinical criteria update

Review Date: 05/15/2020, 07/19/2023

Revision Date: 05/14/2020, 12/08/2021, 07/19/2023