

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Sickle Cell Disease – Oxbryta Drug Quantity Management Policy – Per Rx

- Oxbryta® (voxelotor tablets – Global Blood Therapeutics)

REVIEW DATE: 11/22/2022; selected revision 01/18/2023

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

Dosing

- **Patients ≥ 12 years of age:** 1,500 mg once daily (QD) with or without food.¹
 - **Severe hepatic impairment (Child Pugh C):** 1,000 mg QD.
 - No dose adjustment is need for patients with mild or moderate hepatic impairment.
 - **Drug interactions:** Concomitant use of Oxbryta with strong or moderate cytochrome P450 (CYP)3A4 inducers should be avoided. If concomitant use with these agents cannot be avoided, the dose of Oxbryta should be adjusted to 2,500 mg QD in patients receiving strong CYP3A4 inducers and 2,000 mg in patients receiving moderate CYP3A4 inducers.
- **Patients 4 to < 12 years of age:** Select either the Oxbryta tablets or tablets for oral suspension based on the patient’s ability to swallow tablets and the patient’s weight (Table 1).

Table 1. Recommended Oxbryta Dosing in Patients 4 to < 12 years of age.¹

Body Weight	Oxbryta Dose	Severe Hepatic Impairment* (Child Pugh C)	Concomitant use of Moderate CYP3A4 Inducers	Concomitant use of Strong CYP3A4 Inducers
≥ 40 kg	1,500 mg QD	1,000 mg QD or 900 mg QD	2,000 mg QD or 2,100 mg QD	2,500 mg QD or 2,400 mg QD
20 kg to < 40 kg	900 mg QD	600 mg QD	1,200 mg QD	1,500 mg QD
10 kg to < 20 kg	600 mg QD	300 mg QD	900 mg QD	900 mg QD

* No dose adjustment is required for patients with mild to moderate hepatic impairment; CYP – Cytochrome P450; QD – Once daily.

Availability

Oxbryta is available as 500 mg tablets (bottles of 90), 300 mg tablets (bottles of 60 or 90), and 300 mg tablets for oral suspension (bottle of 60 or 90).¹

POLICY STATEMENT

This Drug Quantity Management program has been developed to manage potential dose escalation of Oxbryta. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Oxbryta® (voxelotor tablets)	500 mg tablets	90 tablets	270 tablets
	300 mg tablets	150 tablets	450 tablets
	300 mg tablets for oral suspension	150 tablets for oral suspension	450 tablets for oral suspension

CRITERIA

Oxbryta 500 mg tablets

1. Approve the requested quantity, not to exceed 150 tablets per dispensing at retail or 450 tablets per dispensing at home delivery, if the patient meets ONE of the following (A or B):
 - A) Patient is ≥ 12 years of age and is taking Oxbryta with a moderate or strong cytochrome P450 (CYP)3A4 inducer; OR
 - B) Patient meets all of the following (i, ii, and iii):
 - i. Patient is 4 to 11 years of age; AND
 - ii. Patient weighs ≥ 40 kg; AND
 - iii. Patient is taking Oxbryta with a moderate or strong CYP3A4 inducer.

Note: Examples of moderate or strong CYP3A4 inducers include, but are not limited to, carbamazepine, enzalutamide, apalutamide, mitotane, phenytoin, rifampin, St. John’s wort, bosentan, efavirenz, etravirine, phenobarbital, and primidone.

Oxbryta 300 mg tablets and tablets for oral suspension

1. Approve the requested quantity, not to exceed 240 tablets/tablets for oral suspension per dispensing at retail or 720 tablets/tablets for oral suspension per dispensing at home delivery, if the patient meets all of the following (A, B, and C):
 - A) Patient is 4 to 11 years of age; AND
 - B) Patient weighs ≥ 40 kg; AND
 - C) Patient is taking Oxbryta with a moderate or strong cytochrome P450 (CYP)3A4 inducer..

Note: Examples of moderate or strong CYP3A4 inducers include, but are not limited to, carbamazepine, enzalutamide, apalutamide, mitotane, phenytoin, rifampin, St. John’s wort, bosentan, efavirenz, etravirine, phenobarbital, and primidone.

REFERENCES

1. Oxbryta® [prescribing information]. San Francisco, CA: Global Blood Therapeutics; October 2022.

CYP – Cytochrome P450.