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: 12/14/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 tablets each), and 300 mg tablets for oral suspension (bottles of 60 or 90 tablets each).[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.

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

Sickle Cell Disease – Oxbryta Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

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; August 2023.

History

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to include the existing quantity limits when the product is obtained via home delivery. **Oxbryta 500 mg tablets:** Criteria were updated to approve "the requested quantity, not to exceed" 150/450 tablets per dispensing at retail and home delivery, respectively, for patients who are taking an interacting drug. Previously, criteria approved exactly 150/450 tablets. **Oxbryta 300 mg tablets for oral suspension:** Criteria were updated to approve "the requested quantity, not to exceed" 240/720 tablets per dispensing at retail and home delivery, respectively, for patients who are taking an interacting drug. Previously, criteria approved exactly 240/720 tablets.	11/22/2022
Selected Revision	**Obryta 300 mg tablets**: This new dosage form was added to the policy with a limit of 150 tablets per prescription at retail or 450 tablets per prescription at home delivery. Override criteria were added to approve the requested quantity, not to exceed 240 tablets per dispensing at retail or 720 tablets for a patient 4 to 11 years of age who weighs ≥ 40 kg and is taking Oxbryta with a moderate or strong CYP3A4 inducer.	01/18/2023

Annual Revision	No criteria changes.	12/14/2023

CYP – Cytochrome P450.