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5.85.038

Section:	Prescription Drugs	**Effective Date:**	July 1, 2023
Subsection:	Hematological Agents	**Original Policy Date:**	December 20, 2019
Subject:	Oxbryta	**Page:**	1 of 4

Last Review Date: June 15, 2023

Oxbryta

Description

Oxbryta (voxelotor)

Background
Oxbryta (voxelotor) is a hemoglobin S (HbS) polymerization inhibitor that binds to HbS with a 1:1 stoichiometry and exhibits preferential partitioning to red blood cells (RBCs). By increasing the affinity of hemoglobin for oxygen, Oxbryta demonstrates dose-dependent inhibition of HbS polymerization. Oxbryta may inhibit RBC sickling, improve RBC deformability, and reduce whole blood viscosity (1).

Regulatory Status
FDA-approved indication: Oxbryta is a hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease in adults and pediatric patients 4 years of age and older (1).

Serious hypersensitivity reactions after administration of Oxbryta have occurred. Clinical manifestations may include generalized rash, urticarial, mild shortness of breath, mild facial swelling, and eosinophilia. If hypersensitivity reactions occur, Oxbryta should be discontinued, and appropriate medical therapy should be administered (1).

The safety and effectiveness of Oxbryta in pediatric patients less than 4 years of age have not been established (1).

Related policies
Adakveo, Endari, Siklos

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Oxbryta may be considered **medically necessary** if the conditions indicated below are met.

Oxbryta may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 4 years of age or older

Diagnosis

Patient must have the following:

Sickle Cell Disease (SCD)

AND ALL of the following:

1. Patients or caregivers have been instructed on how to monitor for hypersensitivity reactions
2. Baseline hemoglobin has been obtained
3. Inadequate treatment response, intolerance, or contraindication to hydroxyurea

Prior – Approval *Renewal* Requirements

Age 4 years of age or older

Diagnosis

Patient must have the following:

Sickle Cell Disease (SCD)

AND ALL of the following:

1. Patients or caregivers have been instructed on how to monitor for hypersensitivity reactions
2. Increase in hemoglobin from baseline

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity
500 mg tablets	450 tablets per 90 days **OR**
300 mg tablets	720 tablets per 90 days
300 mg tablets for oral suspension	

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity

Strength	Quantity
500 mg tablets	450 tablets per 90 days **OR**
300 mg tablets	720 tablets per 90 days
300 mg tablets for oral suspension	

Duration 24 months

Rationale

Summary

Oxbryta (voxelotor) is a hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease in adults and pediatric patients 4 years of age and older. Serious hypersensitivity reactions after administration of Oxbryta have occurred. If hypersensitivity reactions occur, Oxbryta should be discontinued, and appropriate medical therapy should be administered. The safety and effectiveness of Oxbryta in pediatric patients less than 4 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Oxbryta while maintaining optimal therapeutic outcomes.

References

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

Policy History

Date	Action
November 2019	Addition to PA
March 2020	Annual review. Addition of initial requirement to t/f hydroxyurea per SME
September 2021	Annual review and reference update
January 2022	Reduced age requirement from 12 and older to 4 and older per package insert update. Revised quantity chart and added new dosage form of tablets for oral suspension
March 2022	Annual review
June 2022	Annual review
January 2023	Per PI update, addition of 300 mg tablets. Changed policy number to 5.85.038
March 2023	Annual review
June 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 15, 2023 and is effective on July 1, 2023.