UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2183-5
Program	Prior Authorization/Medical Necessity
Medication	Oxbryta™ (voxelotor)
P&T Approval Date	1/2020, 1/2021, 1/2022, 2/2022, 2/2023
Effective Date	5/1/2023; Oxford only: 5/1/2023

1. Background:

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.

This indication is approved under accelerated approval based on increase in hemoglobin (Hb). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

2. Coverage Criteria[a]:

A. Initial Authorization

1. Diagnosis of sickle cell disease

-AND-

2. Patient is ≥ 4 years of age

-AND-

3. **One** of the following:

   a. Patient is currently receiving hydroxyurea therapy

   -OR-

   b. Patient has a history of treatment failure, intolerance, or contraindication to hydroxyurea therapy

-AND-

4. Patient has previously experienced 1 or more sickle cell-related vasoocclusive crises within the previous 12 months

-AND-

5. Baseline hemoglobin (Hb) ≤ 10.5 g/dL

-AND-

6. Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

-AND-

7. Patient is not to receive Oxbryta in combination with Adakveo (crizanlizumab-tmca)

-AND-

8. Prescribed by, or in consultation, with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease

Authorization will be issued for 6 months.

B. Reauthorization

1. Documentation of positive clinical response to Oxbryta therapy as demonstrated by at least **one** of the following:

   a. Increase in hemoglobin (Hb) by ≥ 1 g/dL from baseline
   b. Decrease in indirect bilirubin from baseline
   c. Decrease in percent reticulocyte count from baseline
   d. Patient has experienced a reduction in sickle cell-related vasoocclusive crises

-AND-

2. Patient is not receiving Oxbryta in combination with Adakveo (crizanlizumab-tmca)

-AND-

3. Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

-AND-

4. Prescribed by, or in consultation, with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10)

and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or Notification may be in place.

4. References:

1. Oxbryta [package insert]. South San Francisco, CA: Global Blood Therapeutics, Inc.; October 2022.
2. Vichinsky E, Hoppe CC, Ataga KI, et al. A phase 3 randomized trial of voxelotor in sickle cell disease. N Engl J Med 2019; 381:509-519.

Program	Prior Authorization/Medical Necessity - Oxbryta (voxelotor)
Change Control	
Date	Change
1/2020	New program
1/2021	Annual review. No updates.
1/2022	Annual review with no changes to clinical criteria. Updated reference.
2/2022	Updated background and criteria with expanded indication for patients 4 years to 11 years of age. Updated reference.
2/2023	Annual review with no changes to coverage criteria. Updated reference.