UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Oxbryta

Program	Prior Authorization
Medication	Oxbryta™ (voxelotor)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	1/2020
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	3/2021

1. Background:

Oxbryta is a hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease in adults and pediatric patients 12 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. <u>Initial Authorization</u>

1. Diagnosis of sickle cell disease

-AND-

2. Patient is ≥ 12 years of age

-AND-

3. **<u>One</u>** 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. <u>Reauthorization</u>

1. Documentation of positive clinical response to Oxbryta therapy as demonstrated by at least **<u>one</u>** 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.

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 may be in place.

4. References:

1. Oxbryta [package insert]. South San Francisco, CA: Global Blood Therapeutics, Inc.; November 2019.
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 –Oxbryta (voxelotor)
Change Control	
Date	Change
1/2020	New program
1/2021	Annual review. No changes.