



Manual Prior Authorization

MISSISSIPPI DIVISION OF
MEDICAID

Oxbryta™ is a hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease in adults and pediatric patients ≥ 12 years of age.

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).

Oxbryta will be considered for coverage when all of the following criteria are met:

1. Initial Approval Criteria: (approval issued up to 6 months)

Yes No Diagnosis of sickle cell disease **-AND-**

Yes No Age of patient is within the age range as recommended by the FDA label **-AND-**

Yes No **One** of the following:

a. Oxbryta must be prescribed concurrently with hydroxyurea, unless contraindicated or clinically significant adverse effects are experienced

-OR-

b. Failure of a 6-month trial of hydroxyurea documented by pharmacy claims at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced

AND-

Yes No Prescribed by, or in consultation, with a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease **-AND-**

Yes No Patient has previously experienced 1 or more sickle cell-related vaso-occlusive crises within the previous 12 months with submission of document upon request the number of vaso-occlusive crises within the previous 12 months **-AND-**

Yes No Baseline hemoglobin (Hb) >5.5 to <10.5 g/dL submission upon request **-AND-**

Yes No Patient is not being treated with concomitant chronic blood transfusion therapy **-AND-**

Yes No Baseline bilirubin and percent reticulocyte count submission upon request **-AND-**

Yes No Patient is not to receive Oxbryta in combination with Adakveo (crizanlizumab-tmca) **-AND-**

Yes No Prescriber provides documentation of patient specific treatment goals, which includes monitoring parameters and metric that will be used to determine efficacy **-AND-**

Yes No Dose does not exceed 1,500 mg (3 tablets) per day



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2. Reauthorization Approval Criteria (approval up to 12 months)

Yes No 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 vaso-occlusive crises

Yes No **-AND-**

Yes No Oxbryta must be prescribed concurrently with hydroxyurea, unless contraindicated or clinically significant adverse effects are experienced **-AND-**

Yes No Patient is not receiving Oxbryta in combination with Adakveo (crizanlizumab-tmca) **-AND-**

Yes No Prescribed by or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease **-AND-**

Yes No Dose does not exceed 1,500 mg (3 tablets) per day.

Dosage Forms/Strength

Tablets 500 mg