MISSISSIPPI DIVISION OF MEDICAID

Manual Prior Authorization

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

Oxbryta™ is a hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease in adults and pediatric patients ≥4 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:

□ 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	<u>One</u> 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-
\square Yes \square No Prescribed by, or in consultation, with a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease -AND-	
occlusive cris	Patient has previously experienced 1 or more sickle cell-related vasoses within the previous 12 months with submission of document upon request of vaso-occlusive crises within the previous 12 months -AND-
□ Yes □ No	Baseline hemoglobin (Hb) <10.5 g/dL submission upon request-AND-
□ Yes □ No therapy -ANI	Patient is not being treated with concomitant chronic blood transfusion D-
□ Yes □ No AND-	Baseline bilirubin and percent reticulocyte count submission upon request-
	Patient is not to receive Oxbryta in combination with Adakveo ab-tmca) - AND-
	Prescriber provides documentation of patient specific treatment goals, which nitoring parameters and metric that will be used to determine efficacy -AND-
□ Yes □ No	Dose does not exceed:
	Adults and children 12 years and older: 1,500 mg (3 tablets) per day

Effective: 05-9-2022 V4

Children aged 4 to 11 (weight-based):

40kg or more: 1,500mg/day

20 to 39kg: 900 mg/day

10 to 19 kg: 600mg/day

Lower dosage limits may be required for hepatic impairment.



2. Reauthorization Approval Criteria (approval up to 12 months)
\square Yes \square No 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 vaso-occlusive crises
□ Yes □ No -AND-
\square Yes \square No Oxbryta must be prescribed concurrently with hydroxyurea, unless contraindicated or clinically significant adverse effects are experienced - AND -
\square Yes \square No Patient is not receiving Oxbryta in combination with Adakveo (crizanlizumatmca) -AND-
\square Yes \square 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 maximums as described under initial approval criteria

Dosage Forms/Strengths

Tablets 500 mg

Tablets for oral suspension 300 mg

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