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 ≥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:

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) <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:

Adults and children 12 years and older: 1,500 mg (3 tablets) per day

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)

☐ 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 maximums as described under initial approval criteria.

Dosage Forms/Strengths

Tablets 500 mg

Tablets for oral suspension 300 mg