**FDA INDICATIONS AND USAGE**

Oxbryta™ is indicated to treat sickle cell disease in patients 12 years of age and older. It is a hemoglobin S polymerization inhibitor that was approved under the accelerated pathway. The drug is thought to inhibit red blood cell sickling, improve red blood cell deformity, and reduce whole blood viscosity.

**APPROVAL CRITERIA**

1. Patient is 12 years of age or older AND;
2. Patient has the diagnosis of sickle cell disease AND;
3. Prescribed by or consultation with a hematologist or a provider that specializes in sickle cell disease AND;
4. Documentation that the patient has had at least one vaso-occlusive crisis within the past 6 months AND;
5. Has a documented baseline hemoglobin AND;
6. Patient has tried and failed or has a contraindication to hydroxyurea for at least 3 months.

**DENIAL CRITERIA**

1. Failure to meet approval criteria OR;
2. Patient is receiving concomitant, prophylactic blood transfusions OR;
3. Concomitantly being prescribed with Adakveo.

**CAUTIONS**

- Concomitant use of moderate to strong CYP3A4 inhibitors should be avoided.
- Monitor for hypersensitivity reactions and manage promptly.

**DURATION OF APPROVAL**

- Approval: Up to 3 months
- Reauthorization: Up to 12 months with documentation showing an increase in hemoglobin and/or decrease in vaso-occlusive crisis related emergencies.

**QUANTITY LIMITS**

- 90 – 500mg tablets per 30 days
REFERENCES / FOOTNOTES: