Voxelotor (Oxbryta™) is considered medically necessary when ALL of the following criteria are met:

- Individual is 12 years of age or older
- Documented diagnosis of Sickle Cell Disease (SCD)
- Will be used concurrently with hydroxyurea unless contraindication per FDA label, intolerance (for example, unacceptable toxicity), or otherwise not a candidate (for example, patient who is planning to become pregnant; a pregnant patient; or a patient with an immunosuppressive condition [such as cancer])
- Will not be used concurrently with Adakveo (crizanlizumab)
- Is prescribed by, or in consultation with, a Hematologist or a physician who specializes in Sickle Cell Disease

Coverage for Voxelotor (Oxbryta™) varies across plans. Refer to the customer’s benefit plan document for coverage details.

Initial authorization is up to 6 months.

Voxelotor (Oxbryta™) is considered medically necessary for continued use when ALL of the following criteria are met:

- Documented beneficial clinical response (for example, decrease in sickle cell-related vaso-occlusive crises (VOC), decrease in the need for blood transfusions, decrease in the number of days in the hospital)
- Individual is not receiving Adakveo (crizanlizumab)
- Is prescribed by, or in consultation with, a Hematologist or a physician who specializes in Sickle Cell Disease

**Reauthorization is up to 12 months.**

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

**Voxelotor (Oxbryta™) considered experimental, investigational or unproven for ANY other use including the following:**
- Concurrent use of Oxbryta (voxelotor) with Adakveo (crizanlizumab)

**Note:** Receipt of sample product does not satisfy any criteria requirements for coverage.

*If you’re a Cigna provider, please log in to the Cigna for Health Care Professionals website and search for specific patients to view their covered medications.

### FDA Summary

Oxbryta is indicated for the treatment of sickle cell disease (SCD) 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).

It comes formulated as 500 mg tablets with a recommended dose of 1,500 mg taken orally, once a day.

### Background

Employer group plans may adopt a Prescription Drug List that does not cover certain drugs or biologics unless those products are approved based on a medical necessity review as there are generally covered therapeutic alternatives available. Covered therapeutic alternatives are products usually in the same therapeutic class that can be expected to have equivalent clinical efficacy and safety when administered to patients under the conditions specified in the FDA-approved product information (Label). The number of Covered Alternative Drugs may vary by employer group plan and Prescription Drug Lists (e.g. “closed” versus “open” formulary plan designs).

### Other Covered Uses

AHFS Drug Information 2020 Edition does not support any off-label uses of voxelotor (Oxbryta).

### Experimental, Investigational, Unproven Uses

Compendia and other published clinical studies do not currently support any uses other than the FDA indication. Criteria will be updated as new published data are available.

There is no data to support concomitant use of Adakveo (crizanlizumab) and Oxybryta (voxelotor).

### References
