voxelotor (Oxbryta™)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO171

Description

Voxelotor (Oxbryta) is an orally administered hemoglobin S (HbS) polymerization inhibitor.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
voxelotor (Oxbryta)	500 mg tablets	Sickle Cell Disease	90 tablets/30 days

Initial Evaluation

I. Voxelotor (Oxbryta) may be considered medically necessary when the following criteria are met:
   A. Member is 12 years of age or older; **AND**
   B. Medication is prescribed by, or in consultation with, a hematologist; **AND**
   C. Medication will **not** be used in combination with crizanlizumab-tmca (Adakveo); **AND**
   D. A diagnosis of **sickle cell disease (SCD)** when the following are met:
      1. Documentation of at least **one** vaso-occlusive crisis (VOC) within the previous six months requiring hospitalization, blood transfusion, or other medical intervention; **AND**
      2. Treatment with **BOTH** the following have been ineffective, contraindicated, or both are not tolerated:
         i. Hydroxyurea (generic, Siklos, Droxia) for a minimum duration of six months; **AND**
         ii. L-glutamine (available over-the-counter).

II. Voxelotor (Oxbryta) is considered investigational when used for all other conditions, AND when used in combination with crizanlizumab-tmca (Adakveo).

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**

II. Member is not continuing therapy based off being established on therapy established through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Use of voxelotor (Oxbryta) is **not** in combination with crizanlizumab-tmca (Adakveo); **AND**
IV. Member has exhibited improvement or stability of disease symptoms with documentation of reduced vaso-occlusive crises (VOCs) compared to baseline.

Supporting Evidence

I. Subjects of the pivotal HOPE trial (Hemoglobin Oxygen Affinity Modulation to Inhibit HbS Polymerization) were between 12 to 65 years of age with confirmed sickle cell disease with documentation of one to 10 vaso-occlusive events within the past 12 months. Hemoglobin levels among subjects prior to therapy were between 5.5 and 10.5 g/dL. Approximately two-thirds of subjects included in the HOPE trial were established on hydroxyurea at baseline.
II. The HOPE trial reported a decrease in indirect bilirubin level of 29.1% and a relative change in percent reticulocytes of 20% less in the 1500 mg voxelotor (Oxbryta) group.
III. Efficacy outcomes to support use of voxelotor (Oxbryta) in sickle cell disease include increase in hemoglobin by 24 weeks. There no data to support an increase in hemoglobin level results in a reduction in vaso-occlusive events, or other complications related to sickle cell disease. Hemoglobin represents one of many factors contributing to VOCs.
IV. Acute complications and symptoms occur intermittently in sickle cell disease and throughout its course. These complications include vaso-occlusive pain crises (VOCs), acute chest syndrome, aplastic crisis, hemolytic crisis, and the pooling of blood within bodily organs.
V. Vaso-occlusive crises (VOCs) include stroke, severe pain, kidney and other organ and/or tissue damage for which there is no other explanation than vaso-occlusive crisis.
VI. Transfusion protocol is considered the most effective therapy for secondary stroke prophylaxis. If this contraindicated or ineffective, hydroxyurea is introduced.
VII. Hydroxyurea
    - Generic hydroxyurea is considered first-line in the treatment of sickle cell disease.
    - Typically offered to patients with three or greater sickle cell-associated moderate-to-severe crises within the last 12 months.
    - Has been shown to be disease modifying at reducing the rate of pain episodes, stroke, transfusion requirement, and mortality.
    - Has been shown to reduce the number of vaso-occlusive crises (VOCs) and hospitalizations.
    - Approximately two-thirds of subjects included in the HOPE trial (Hemoglobin Oxygen Affinity Modulation to Inhibit HbS Polymerization) were established on hydroxyurea at baseline.
VIII. L-glutamine

- Typically considered in patients who have at least two vaso-occlusive crises (VOCs) per year, despite maximally tolerated hydroxyurea dose, and considered against cost.
- Was approved to reduce acute complications of sickle cell disease (VOCs).
- Monotherapy is considered in patients who do not tolerate hydroxyurea. Over-the-counter products are available as well as in a prescription product L-glutamine (Endari)

IX. Both hydroxyurea and L-glutamine have evidence to support disease-modifying activity and the reduction of VOC or complications related to disease.

Investigational or Not Medically Necessary Uses

X. There is currently limited to no data to support the safety and efficacy of concomitant use of voxelotor (Oxbryta) with crizanlizumab-tmca (Adakveo).

References

1. Oxbryta [Package Insert]. Global Blood Therapeutics. San Francisco, CA. November, 2019
2. Vichinsky E, Hoppe CC, Ataga KI et al. A phase 3 randomize trial of voxelotor in sickle cell disease. N Engl J Med. 2019; 381: 509-19.
3. Buchanan GR, Yawn BP, Afenyi-Annan AN et al. Evidence-based management of sickle cell disease: expert panel report. National Heart, Lung, and Blood Institute. 2014.

Policy Implementation/Update:

Action and Summary of Changes	Date
Policy created	02/2020