## Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

## Voxelotor (Oxbryta)

#### Notes:

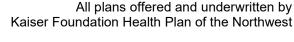
- ^ Treatment failure is defined as lack of clinically meaningful reduction in frequency of vaso-occlusive crises after 6 to 12 months of treatment.
- Prescribing hematologist should assess for efficacy, tolerance, and adherence at least every 6
  months; Discontinuation of Voxelotor (Oxbryta) may be considered if there is lack of efficacy (no
  increase in Hb that leads to a decrease in transfusion requirement and/or symptoms) after 6 to 12
  months, and/or Intolerance to medication, and/or non-adherence to medication or follow-up labs and
  assessments, and/or patient is breastfeeding; Need for treatment should be re-assessed every 6
  months; Dose adjustment may be required when used concurrently with other CYP3A4
  substrates/inhibitors/inducers.

<u>Initiation (new start) criteria:</u> Non-formulary **Voxelotor (Oxbryta)** will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Documented treatment failure<sup>^</sup> with: Hydroxyurea (generic Droxia) AND L-glutamine (Endari);
  - **-OR-** known or predicted intolerance to Hydroxyurea (generic Droxia) **AND** L-glutamine (Endari).
- Patient is at least 12 years of age
- Diagnosed with Hb SS disease (sickle cell anemia) or HbS beta thalassemia (documented by Hb electrophoresis) -AND
  - o At least one of the following:
    - transfusion-dependent anemia with chronic iron overload or with alloantibodies -OR-
    - ii. symptomatic anemia without transfusion-dependence -OR-
    - iii. pulmonary hypertension and hypoxia -OR-
    - iv. Hb level 10.5 g/dL or lower prior to treatment with voxelotor
- No history of cerebrovascular accident (CVA) or acute chest syndrome (ACS) requiring exchange or chronic transfusion
- Alanine aminotransferase (ALT) less than 4x upper limit of normal (ULN)
- Renal function with estimated glomerular filtration rate (eGFR) greater than 30 mL/min/1.73 m<sup>2</sup>
- Patient is not breastfeeding

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Revised: 07/11/24 Effective: 09/05/24





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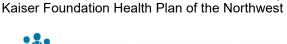
### Voxelotor (Oxbryta)

<u>Continued Use Criteria:</u> Non-formulary **Voxelotor (Oxbryta)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Initial use criteria continue to be met
- Documented efficacy defined as increase in Hb that leads to a decrease in transfusion requirement and/or symptoms after 6 to 12 months.

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