SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

<u>Directions</u>: <u>The prescribing physician must sign and clearly print name (preprinted stamps not valid)</u> on this request. All other information may be filled in by office staff; <u>fax to 1-800-750-9692</u>. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. <u>If the information provided is not</u> complete, correct, or legible, the authorization process may be delayed.

Drug Requested: Oxbryta[®] (voxelotor)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name:	
Member Sentara #:	Date of Birth:
Prescriber Name:	
Prescriber Signature:	
Office Contact Name:	
Phone Number:	
DEA OR NPI #:	
DRUG INFORMATION: Authoriza	ation may be delayed if incomplete.
	Length of Therapy:
Diagnosis:	ICD Code, if applicable:
Weight (kg):	

Part A

- Vaso-occlusive crises (VOC): defined as acute episodes of pain that were caused by a vaso-occlusive event that resulted in a visit to a medical facility and treatment with oral or parenteral opioids or parenteral nonsteroidal anti-inflammatory drugs. ICD codes for VOC and pharmacy claims from within the last 12 months will be verified.
- ICD CODES for Crisis while in ER/INPATIENT: 282.42, 282.62, 282.64, 282.69, D57.0, D57.00, D57.01, D57.02, D57.21, D57.211, D57.212, D57.219, D57.41, D57.411, D57.419 D57.3, D57.412, D57.81, D57.811, D57.812, D57.819

Recommended Dosing:

- Adults and pediatric patients 12 years of age or older: 1,500 mg orally once daily
- Children 4 years of age to less than 12 years of age:
 - o 10 to < 20 kg: 600 mg orally once daily
 - o 20 to < 40 kg: 900 mg orally once daily
 - o \geq 40 kg: 1,500 mg orally once daily

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- Provider is a hematologist, has been in consultation with one, or a specialist in treating patients with sickle cell disease
- □ Member is 4 years of age or older
- □ Member has a confirmed medical history or diagnosis of sickle cell disease:
 - □ HbSS □ HbSC □ HbSB0-thalassemia □ HbSB+-thalassemia
 - Other: _____
- □ Member has experienced at least 1 vaso-occlusive crises (defined in Part A) within the preceding 12 months as determined by medical documentation with ICD codes
- <u>ONE</u> of the following must be met:
 - □ Oxbryta[®] (voxelotor) therapy will be taken concomitantly with hydroxyurea
 - □ Member had an insufficient response to at least <u>90 consecutive days</u> of treatment with hydroxyurea within 12 months of this request (defined as >2 VOCs as detailed in Part A; paid pharmacy claims for hydroxyurea and Droxia within the last 12 months will be verified)
 - □ Member cannot take hydroxyurea due to contraindications of severe bone marrow depression (e.g., leukopenia [<2,500/mm³], thrombocytopenia [<100,000/mm³], or severe anemia that requires transfusion (Labs completed within the last 30 days documenting contraindication must be submitted)
- □ Member has symptomatic anemia with a baseline hemoglobin level between ≥6.0 g/dL and ≤10.5 g/dL (Labs completed within the last 30 days documenting hemoglobin level must be submitted)
- □ A baseline measure of blood counts has been submitted, to include indirect bilirubin and percent reticulocytes (Labs completed within the last 30 days must be submitted)
- Member is <u>NOT</u> receiving regularly scheduled therapy from a chronic red blood cell transfusion program (Recent chart notes detailing medical history, transfusion history, and clinical plans must be submitted with this request)
- □ Requested medication is <u>NOT</u> initiated during an aplastic episode (hemoglobin concentration 2 g/dL or more below baseline or less than 6 g/dL when the baseline is not recorded or known)
- □ Member is <u>NOT</u> concomitantly receiving Adakveo[®] (crizanlizumab) or Endari[®] (L-glutamine oral powder). If member is currently on Adakveo[®] or Endari[®], then Oxbryta[®] will be denied.

<u>Reauthorization</u>: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- <u>ONE</u> of the following continues to be met:
 - Oxbryta[®] (voxelotor) therapy will be taken concomitantly with hydroxyurea

- □ Member had an insufficient response to at least <u>90 consecutive days</u> of treatment with hydroxyurea within 12 months of this request (defined as >2 VOCs as detailed in Part A; paid pharmacy claims for hydroxyurea and Droxia within the last 12 months will be verified)
- Member cannot take hydroxyurea due to contraindications of severe bone marrow depression (e.g., leukopenia [<2,500/mm³], thrombocytopenia [<100,000/mm³], or severe anemia that requires transfusion (Labs completed within the last 30 days documenting contraindication must be submitted)
- □ Member's hemoglobin levels have demonstrated an increase >1g/dL from baseline (Labs completed within the last 30 days documenting hemoglobin level must be submitted)
- Documentation of a positive clinical response to Oxbryta[®] (voxelotor) therapy demonstrated by <u>ONE</u> of the following must be met (Labs completed within the last 30 days must be submitted):
 - Decrease in indirect bilirubin from baseline
 - Decrease in percent reticulocyte count from baseline

Medication being provided by Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria. *<u>Previous therapies will be verified through pharmacy paid claims or submitted chart notes.</u>*