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 (<u>including phone and fax #s</u>) on this form is correct. <u>If the information provided is not complete, correct, or legible, the authorization process may be delayed.</u>

Drug Requested: Oxbryta[®] (voxelotor)

MEMBER & PRESCRIBER INFO	DRMATION: Authorization may be delayed if incomplete.				
Member Name:					
	Date of Birth:				
Prescriber Name:					
Prescriber Signature:					
Office Contact Name:					
Phone Number:	Fax Number:				
DEA OR NPI #:					
	on may be delayed if incomplete.				
Drug Form/Strength:					
	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
 - $o \ge 40 \text{ kg}$: 1,500 mg orally once daily

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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.

<u>niti</u>	<u>al Authorization</u> : 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 \geq 6.0 g/dL and \leq 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 \underline{NOT} 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.				
	uthorization: 12 months. Check below all that apply. All criteria must be met for approval. To				
	ort each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be ded or request may be denied.				
	□ <u>ONE</u> of the following continues to be met:				
	☐ Oxbryta [®] (voxelotor) therapy will be taken concomitantly with hydroxyurea				

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- ☐ 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.

*Previous therapies will be verified through pharmacy paid claims or submitted chart notes. *