AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Oxbryta® (voxelotor)

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

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

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:
  - 10 to < 20 kg: 600 mg orally once daily
  - 20 to < 40 kg: 900 mg orally once daily
  - ≥ 40 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.

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
- ❑ **ONE** of the following must be met:
  - ❑ Oxbryta® (voxelotor) therapy will be taken concomitantly with hydroxyurea
  - ❑ Member had an insufficient response to at least 90 consecutive days 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/mm^3], thrombocytopenia [<100,000/mm^3], 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 **NOT** 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 **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 **NOT** concomitantly receiving Adakveo® (crizanlizumab) or Endari® (L-glutamine oral powder). **If member is currently on Adakveo® or Endari®, then Oxbryta® will be denied.**

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Reauthorization: 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.

- ❑ **ONE** of the following continues to be met:
  - ❑ Oxbryta® (voxelotor) therapy will be taken concomitantly with hydroxyurea
  - ❑ Member had an insufficient response to at least 90 consecutive days 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/mm^3], thrombocytopenia [<100,000/mm^3], 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 **ONE** 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.****