Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2020**
Policy Number: PA.CP.PHAR.451	**Effective Date: 04/15//2020** **Revision Date: 04/15/2020**
Policy Name: Voxelotor (Oxbryta)	

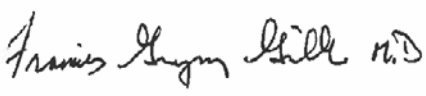
Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

New Policy Created

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Voxelotor (Oxbryta)

Reference Number: CP.PHAR.451
Effective Date: 04/2020
Last Review Date: 04/2020

Revision Log

Description
Voxelotor (Oxbryta™) is a hemoglobin S (HbS) polymerization inhibitor.

FDA Approved Indication(s)
Oxbryta is indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 12 years of age and older.

This indication is approved under accelerated approval based on the increase in hemoglobin (Hb). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Oxbryta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Sickle Cell Disease (must meet all)**:**

1. Diagnosis of SCD with one of the following genotypes (a, b, c, or d):
   a. Homozygous hemoglobin S;
   b. Hemoglobin Sβ^0-thalassemia;
   c. Hemoglobin Sβ^+-thalassemia;
   d. Hemoglobin SC;
2. Age ≥ 12 years;
3. Prescribed by or in consultation with a hematologist;
4. Hb level ≥ 5.5 and ≤ 10.5 g/dL;
5. Member meets one of the following (a or b):
   a. Member has experienced at least 1 vaso-occlusive crisis (VOC) within the past 6 months while on hydroxyurea at up to maximally indicated doses (*see Appendix D*);
   b. Member has intolerance* or contraindication to hydroxyurea and has experienced at least 1 VOC within the past 12 months (*see Appendix D*);
   **Myelosuppression and hydroxyurea treatment failure: Myelosuppression is dose-dependent and reversible and does not qualify for treatment failure. NIH guidelines recommend a 6 month trial on the maximum tolerated dose prior to considering discontinuation due to treatment failure, whether due to lack of adherence or failure to respond to therapy. A lack of increase in mean corpuscular volume (MCV) and/or fetal hemoglobin (HbF) levels is not indication to discontinue therapy.*
6. For age ≥ 16 years: Failure of Adakveo®, unless contraindicated or clinically significant adverse effects are experienced;

7. Failure of blood transfusion(s), unless contraindicated (e.g., cutaneous ulcers, iron overload);
8. Oxbryta is prescribed concurrently with hydroxyurea, unless contraindicated or clinically significant adverse effects are experienced;
9. Oxbryta is not prescribed concurrently with Adakveo;
10. Dose does not exceed 1,500 mg (3 tablets) per day.

Approval duration: 2 months

B. Other diagnoses/indications

1. Refer to the off-label use policy: PA.CP.PMN.53

II. Continued Therapy

A. Sickle Cell Disease (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy as evidenced by an increase in Hb level from baseline of at least 1 g/dL;
3. Oxbryta is prescribed concurrently with hydroxyurea, unless contraindicated or clinically significant adverse effects are experienced;
4. Oxbryta is not prescribed concurrently with Adakveo;
5. If request is for a dose increase, new dose does not exceed 1,500 mg (3 tablets) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
Hb: hemoglobin
SCD: sickle cell disease
VOC: vaso-occlusive crisis

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
hydroxyurea (Droxia®)	*Age ≥ 18 years* Initial: 15 mg/kg/day PO single dose; based on blood counts, may increase by 5 mg/kg/day every 12 weeks to a max 35 mg/kg/day	35 mg/kg/day
hydroxyurea (Siklos®)	*Age ≥ 2 years* Initial: 20 mg/kg/day PO QD; based on blood counts, may increase by 5 mg/kg/day every 8 weeks or if a painful crisis occurs	35 mg/kg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindicaton(s): prior drug hypersensitivity to Oxbryta or excipients
- Boxed warning(s): none reported

Appendix D: General Information

- A VOC is defined as a previously documented episode of acute painful crisis or acute chest syndrome (ACS) for which there was no explanation other than VOC that required prescription or healthcare professional-instructed use of analgesics for moderate to severe pain.
- Myelosuppression and hydroxyurea treatment failure: Myelosuppression is dose-dependent and reversible and does not qualify for treatment failure. NIH guidelines recommend a 6 month trial on the maximum tolerated dose prior to considering discontinuation due to treatment failure, whether due to lack of adherence or failure to respond to therapy. A lack of increase in mean corpuscular volume (MCV) and/or fetal hemoglobin (HbF) levels is not indication to discontinue therapy.
- Hydroxyurea dose titration: Members should obtain complete blood counts (CBC) with white blood cell (WBC) differential and reticulocyte counts at least every 4 weeks for titration. The following lab values indicate that it is safe to increase dose.
  - Absolute neutrophil count (ANC) in adults ≥ 2,000/uL, or ANC ≥ 1,250/uL in younger patients with lower baseline counts
  - Platelet counts ≥ 80,000/uL

  If neutropenia or thrombocytopenia occurs: hydroxyurea dosing is held, CBC and WBC differential are monitored weekly, members can restart hydroxyurea when values have recovered.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
SCD	1,500 mg PO QD with or without food. Oxbryta may be given with or without hydroxyurea.	1,500 mg/day

VI. Product Availability

Tablet: 500 mg

VII. References

1. Oxbryta Prescribing Information. South San Francisco, CA: Global Blood Therapeutics, Inc.; November 2019. Available at: https://www.oxbryta.com/. Accessed March 4, 2020.
2. Vichinsky E, Hoppe CC, Ataga KI, et al. A phase 3 randomized trial of voxelotor in sickle cell disease. N Engl J Med. 2019 Aug 8;381(6):509-519.
3. Yawn BP, Buchanan GR, Afenyi-Annan AN, et al. Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members. JAMA. 2014 Sep 10;312(10):1033-48.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, CO: Thomson Healthcare. Updated periodically. Accessed December 4, 2019.

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

The following is a list of diagnosis codes that support coverage for the applicable covered procedure code(s).

ICD-10-CM Code	Description
D57.0*	Hb-SS disease with crisis
D57.1	Sickle-cell disease without crisis
D57.2*	Sickle-cell/Hb-C disease
D57.4*	Sickle-cell thalassemia

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04/2020	