



Prior Authorization Review Panel

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: Aetna Better Health	Submission Date: 6/1/2020
Policy Number:	Effective Date: 8/1/2020 Revision Date: 5/2020
Policy Name: Oxbryta (Non-PDL)	
Type of Submission – <u>Check all that apply:</u>	
<input checked="" type="checkbox"/> New Policy <input type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review – No Revisions <input type="checkbox"/> Statewide PDL	
<p>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</p> <p>Please provide any clarifying information for the policy below: Adopting DHS criteria. Thank you.</p>	

Last Review: 5/2020
Current PARP Approval: 8/2020



Name of Authorized Individual (Please type or print): Natalie Nkurunziza, Pharm.D.	Signature of Authorized Individual: <i>Natalie Nkurunziza, Pharm.D.</i>
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AETNA BETTER HEALTH®

Prior Authorization guideline for Oxbryta (Non-PDL)

Authorization guidelines

Criteria to receive Oxbryta (voxelotor) requires all the following:

- A. Diagnosis of sickle cell disease
- B. Member is 12 years of age or older
- C. Prescribed by or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease
- D. Failure of a 3-month trial of hydroxyurea or clinical rationale as to why it cannot be used
- E. Baseline hemoglobin level between 5.5 and 10.5g/dL within the past 3 months
- F. Member has had 1 or more vaso-occlusive crises in the past 12 months
- G. Member is not receiving regular red-cell transfusion therapy, has not received a transfusion in the past 60 days, and has not been hospitalized for vaso-occlusive crisis within 14 days
- H. Adakveo will not be used concurrently

Criteria for renewal: Documentation showing there has been a sustained hemoglobin increase from baseline of more than 1g/dL

Approval Duration

Initial Approval: 6 (six) months

Renewal: 12 months

Quantity Limit

3 tablets per day

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Medically Necessary — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member's family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

References:

1. Oxbryta™ [package insert]. South San Francisco, CA: Global Therapeutics; Revised November 2019. <https://www.oxbryta.com/pdf/prescribing-information.pdf>. Accessed March 30, 2020.
2. National Institutes of Health (NIH): National Heart, Lung, and Blood Institute (NHLBI). Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Accessed April 1, 2020.
3. Vichinsky, E.P. (2020). Disease-modifying therapies for prevention of vaso-occlusive pain in sickle cell disease. In M. R. DeBaun (Ed.), UpToDate. Retrieved April 1, 2020 from: <https://www.uptodate.com/contents/disease-modifying-therapies-for-prevention-of-vaso-occlusive-pain-in-sickle-cell-disease>.

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