MASSACHUSETTS

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Pharmacy Medical Policy

Medications for Sickle Cell and Beta Thalassemia

Table of Contents

Policy Number: 083

BCBSA Reference Number: None

Related Policies

- Quality Care Dosing guidelines apply to the following medications and can be found in Medical Policy #621A

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

Prior Authorization Information

☒ **Prior Authorization** ☐ **Step Therapy** ☒ **Quality Care Dosing**		**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289 Policy last updated **1/2024**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ **Rx** ☐ **MED**	**To request for coverage:** Physicians may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below. **Blue Cross Blue Shield of Massachusetts** **Pharmacy Operations Department** 25 Technology Place Hingham, MA 02043 **Individual Consideration:** Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration
Policy applies to Commercial Members: • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary		

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

Standard Formulary	
Drug	**Formulary Status**
Reblozyl ® (luspatercept)	PA Required
Adakveo ® (crizanlizumab)	PA Required
Oxbryta ™ (voxelotor)	PA Required

We may cover Adakveo ® **(**crizanlizumab**)** for the treatment of vasoocclusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease when **all** of the following criteria are met:

- Patient is ≥ 16 years old, **AND**
- Documented diagnosis of diagnosis of sickle cell disease (including HbSS, HbSC,HbSβ^0-thalassemia or HbSβ^+-thalassemia patients), **AND**
- Is not receiving regularly scheduled blood (RBC) transfusion therapy (also termed chronic, prophylactic, or preventive transfusion), **AND**
- Have experienced between 2 and 10 sickle cell-related pain crises within the preceding 12 months, **AND**
- Hemoglobin is >4.0 g/dL;

If the above conditions are met the first approval can be for up to 6 months

Continuation Criteria for Adakveo ® **(**crizanlizumab**)**

Documentation including proof of the decrease of vasoocclusive crises (VOCs) from the original 6-month period or continued decreased number of vasoocclusive crises (VOCs) achieved from the original 6-month period. If continuation is approved the authorization may be approved for up to 12 months.

We may cover Reblozyl ® **(**luspatercept**)** for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions when **all** of the following criteria are met:

- Patient is ≥ 18 years old, **AND**
- Documented diagnosis of β-thalassemia or Hemoglobin E/β-thalassemia, **AND**
- Does not have a diagnosis of Hemoglobin S/β-thalassemia or alpha (α)-thalassemia, **AND**
- Regularly transfused, defined as 6-20 Red Blood Cell (RBC) units in the most recent 24 weeks, **AND**
- No transfusion-free period for ≥ 35 days during the most recent 24 weeks, **AND**
- Platelet count < 1000 x 10^9/L

We may also cover Reblozyl ® **(**luspatercept**)** for the treatment of anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions when **all** of the following criteria are met:

- Patient is ≥ 18 years old, **AND**
- Has not used any previous erythropoiesis stimulating agent use (ESA-naïve), **AND**
- Confirmed diagnosis of very low- to intermediate-risk myelodysplastic syndromes (MDS)

We may also cover Reblozyl ® **(**luspatercept**)** for the treatment of anemia in low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) when **all** of the following criteria are met:

- Patient is ≥ 18 years old, **AND**
- Failed therapy with an erythropoiesis stimulating agent, **AND**
- requiring 2 or more red blood cell units over 8 weeks in adult patients

If the above conditions are met the first approval is for 12 weeks

Continuation Criteria for Reblozyl ® **(**luspatercept**)**

Documentation including proof of the decrease of RBC transfusions from the original 12-week period or continued decreased utilization of RBC transfusions achieved from the original 12-week period. If continuation is approved the authorization may be approved for up to 12 months.

We may cover Oxbryta ™ **(**voxelotor**)** for the treatment of sickle cell disease (SCD) in adults and pediatric patients 4 years of age and older when **all** of the following criteria are met:

- Patient is ≥ 4 years old, **AND**
- Documented diagnosis of diagnosis of sickle cell disease, **AND**
- Is not receiving regularly scheduled blood (RBC) transfusion therapy (also termed chronic, prophylactic, or preventive transfusion), **AND**
- Hemoglobin (Hb) ≥5.5 and ≤10.5 g/dL

If the above conditions are met the first approval can be for up to 6 months

Continuation Criteria for Oxbryta ™ **(**voxelotor**)**

Documentation including proof of the increase of Hemoglobin of >1.0 g/dL from the original 6-month period or continued Hemoglobin increase achieved from the original 6-month period. If continuation is approved the authorization may be approved for up to 12 months.

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

For non-formulary/non-covered medications, requests must meet criteria above and the member must have had a previous treatment failure with or a contraindication to two covered formulary alternatives when available.

We do not cover the medications listed above for other conditions not listed above.

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this service.

Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Policy History

Date	Action
1/2024	Updated new indications for Reblozyl ®
7/2023	Reformatted Policy.
2/2022	Updated age range of Oxbryta ™.
6/2020	Updated new indications for Reblozyl ®
2/2020	Implement new policy for Reblozyl ®, Adakveo ®, & Oxbryta ™.

References

1. Reblozyl® [package insert]. Summit, NJ: Celgene Corporation: 3/2019.
2. Adakveo ® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation: 11/2019.
3. Oxbryta™ [package insert]. South San Francisco, CA: Global Blood Therapeutics, Inc.: 12/2019.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf