Mass General Brigham
Health Plan

Beta Thalassemia, Myelodysplastic Syndrome and Sickle Cell Disease Agents
Adakveo (crizanlizumab-tmca)
Reblozyl (luspatercept-aamt)
Effective 06/01/2025

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Notes	Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Adakveo is indicated to reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease.

Reblozyl is indicated for the treatment of:

- Anemia in adult patients with beta thalassemia who require regular red blood cell transfusions,
- Anemia without previous erythropoiesis stimulating agent use in adult patients with very low- to intermediate-risk myelodysplastic syndromes who may require regular red blood cell transfusions,
- Anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who new to the plan who are currently receiving treatment with requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted if the member meets all following criteria and documentation has been submitted:

Adakveo (crizanlizumab-tmca)

1. Diagnosis of sickle cell disease
2. Member is ≥ 16 years of age
3. Prescriber is a hematologist or consult notes from a hematologist are provided

4. Member has experienced two or more sickle cell crises in the previous 12 months
5. **ONE** of the following:
    a. Inadequate response to hydroxyurea therapy at the maximally tolerated dose (up to a max of 35 mg/kg/day or until mild myelosuppression [e.g., ANC 2,000/uL to 4,000/uL, platelet count < 80,000/uL, reticulocyte count < 80 x 10^9/L]) for at least three months
    b. Adverse reaction or contraindication to hydroxyurea
6. Member's current weight

Reblozyl (luspatercept-aamt)
Beta-thalassemia
1. Documentation is submitted supporting a diagnosis of transfusion-dependent β-thalassemia (e.g., genetic test, medical records noting requirement of regular blood transfusions and/or chronic iron chelator use)
2. Member is ≥ 18 years of age
3. Prescriber is a hematologist or consult notes from a hematologist supporting the use of Reblozyl are provided
4. Member's current weight

Myelodysplastic syndromes (MDS) Associated Anemia
(inclusive of Myelodysplatic syndromes with ring sideroblasts [MDS-RS] or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis [MDS/MPN-RS-T])
1. Diagnosis of myelodysplastic syndromes associated anemia
2. Member is ≥ 18 years of age
3. Prescriber is a hematologist or consult notes from a hematologist supporting use of Reblozyl are provided
4. Member's current weight

<u>Continuation of Therapy</u>
Adakveo: Reauthorization will require physician documentation of positive response to therapy as evidenced (e.g., decrease in VOCs, reduction in need for pain management, decrease in hospitalizations).

Reblozyl: Reauthorization will require physician documentation of a positive response to therapy (decrease in transfusion requirements).

Limitations
1. Initial approvals and reauthorizations will be granted for 6 months.

References

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3. Centers for Disease Control and Prevention. Thalassemia [webpage on the internet]. Atlanta (GA): Centers for Disease Control and Prevention; 2021 [cited 2022 Mar 23]. Available from: https://www.cdc.gov/ncbddd/thalassemia/
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11. Adakveo [package insert]. East Hanover (NJ): Novartis Pharmaceutics, Inc.; 2024 Jun.
12. FDA approves new Treatment for Sickle Cell disease [press release on the internet]. Rockville (MD): Food and Drug Administration (US); 2017 Jul 07 [cited 2022 Mar 23]. Available from https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm566084.htm.
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14. da Guarda CC, Yahouédéhou SCMA, Santiago RP, Neres JSDS, Fernandes CFL, Aleluia MM, Figueiredo CVB, et al. Sickle cell disease: A distinction of two most frequent genotypes (HbSS and HbSC). PLoS One. 2020 Jan 29;15(1):e0228399.

Review History

03/18/2020 – Created and Reviewed P&T Mtg (effective 6/1/20)
11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes
01/11/23 - Reviewed and updated for Jan P&T. Matched MH UPPL criteria. Added criteria for drugs: Endari, Oxbryta, Reblozyl, Siklos. Updated Adakveo criteria. Effective 4/1/23.
09/13/23 – Reviewed and updated for P&T. Updated Oxbryta tablets for oral suspension for age due to medical necessity for consistency. Brand preferred and mandatory generic language was added under Limitations. Effective 10/2/23.
05/15/2025 – Reviewed and updated for P&T. Performed annual medical criteria review. Policy has been updated to better reflect agents with prior authorization on medical benefit. Endari, Oxbryta, and Siklos were pharmacy benefit only and have thus been removed. Updated formatting & references accordingly. Removed requirement trial with 1 erythropoiesis stimulating agent and documentation that member has RBC transfusions in that past 8 weeks for Reblozyl. Effective 6/1/25