Mass General Brigham
Health Plan

Rytelo (imetelstat)
Effective 03/01/2025

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		
Exceptions	N/A		

Overview
Rytelo (imetelstat) is an oligonucleotide telomerase inhibitor indicated for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic transfusions with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents.

Coverage Guidelines
Authorization may be granted for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication and are stable, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:
1. Documented diagnosis of myelodysplastic syndrome that is low- to intermediate risk
2. Requested medication is prescribed by or in consultation with a hematologist or oncologist
3. Member is 18 years of age or older
4. Member meets ONE of the following:
    a. Absolute neutrophil count (ANC) greater than or equal to $1.5x10^9$/L
    b. Platelet count greater than or equal to $75x10^9$/L
5. Member has required four or more red blood cell units over eight weeks
6. Member meets ONE of the following:
    a. Member has had no response to erythropoiesis-stimulating agents
    b. Member has lost response to erythropoiesis-stimulating agents
    c. Member has is ineligible for treatment with erythropoiesis-stimulating agents

<u>Continuation of Therapy</u>
Requests for reauthorization will be approved when the following criteria are met:

1. Documentation member has had a positive response to therapy (e.g., decrease in red blood cell transfusions)

Limitations

1. Initial requests will be approved for 6 months
2. Reauthorization requests will be approved for 12 months

References

1. Fenaux P, Haase D, Santini V, et al. Myelodysplastic syndromes: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol*. 2021;32(2):142-156. doi:10.1016/j.annonc.2020.11.002
2. Institute for Clinical and Economic Review (ICER): Imetelstat for anemia in myelodysplastic syndrome: Effectiveness and value. Evidence Report. July 2, 2024. ICER. https://icer.org/wp-content/uploads/2024/01/MDS_Revised-Report_For-Publication_07022024.pdf
3. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology – Myelodysplastic Syndromes. v3.2024. NCCN. Accessed July 25, 2024. https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf
4. Platzbecker U, Santini V, Fenaux P, et al. Imetelstat in patients with lower-risk myelodysplastic syndromes who have relapsed or are refractory to erythropoiesis-stimulating agents (IMerge): A multinational, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2024;403(10423):249-260. doi:10.1016/S0140-6736(23)01724-5
5. Rytelo (imetelstat) [prescribing information]. Foster City, CA: Geron Corporation; June 2024.
6. Steensma DP, Fenaux P, Van Eygen K, et al. Imetelstat achieves meaningful and durable transfusion independence in high transfusion-burden patients with lower-risk myelodysplastic syndromes in a Phase II study. *J Clin Oncol*. 2021;39(1):48-56.

Review History

12/11/2024 – Reviewed at December P&T. Effective 3/1/2025.