

**Beta Thalassemia, Myelodysplastic Syndrome and Sickle Cell Disease Agents**  
**Rytelo (imetelstat)**  
**Effective 09/01/2025**

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Contact Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

### Overview

Rytelo (imetelstat) is an oligonucleotide telomerase inhibitor that blocks the interaction between telomerase and telomeres, leading to the increased destruction of malignant cells with high telomerase activity. This inhibition can improve hematopoiesis in the bone marrow. Imetelstat is currently indicated for the treatment for transfusion-dependent anemia in lower-risk MDS patients who have not responded to, lost response to, or are ineligible for ESAs.

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan 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 for members when all the following criteria are met:

1. Diagnosis of low-to intermediate-1 risk myelodysplastic syndromes (MDS)
2. Member is  $\geq 18$  years of age
3. Prescriber is a hematologist or consult notes from specialist are provided
4. Member has required  $\geq 4$  RBC transfusions in the last eight weeks
5. Inadequate response or adverse reaction to ONE or contraindication to ALL erythropoiesis stimulating agents (e.g. epoetin, darbepoetin)
6. If member has MDS with ring sideroblasts (RS), inadequate response, adverse reaction or contraindication to Reblozyl (luspatercept)
7. If member has MDS associated with a del 5q cytogenic abnormality, inadequate response, adverse reaction or contraindication to lenalidomide
8. Dosing is appropriate per FDA labeling

### Continuation of Therapy

Prescriber must provide documentation of positive response to therapy (e.g., decrease in transfusion requirements).

**Limitations**

1. Authorizations will be granted for 6 months.

**References**

1. Sekeres MA, Platzbecker U. Myelodysplastic syndromes/neoplasms (MDS): Overview of diagnosis and management. In: Larson RA (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2024 [cited 2024 Jun 28]. Available from: <http://www.utdol.com/utd/index.do>.
2. Cogle CR. Incidence and Burden of the Myelodysplastic Syndromes. Curr Hematol Malig Rep. Sep 2015;10(3):272-81. doi:10.1007/s11899-015-0269-y.
3. NCCN. Myelodysplastic Syndromes. Version 3.2024; 2024 Jul 25 [cited 2024 Aug 21]. Available from: [https://www.nccn.org/professionals/physician\\_gls/pdf/mds.pdf](https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf).
4. Rytelo® [prescribing information]. Foster City (CA): Geron Corporation; 2024 Jun.

**Review History**

12/11/24 – Created for P&T. Adopted MH criteria for Rytelo available through MBO. Effective 1/6/25

8/13/25 – Reviewed and updated for P&T. Minor formatting updates only. Effective 9/1/25

