Reference number(s)
6522-A

Specialty Guideline Management
Rytelo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rytelo	imetelstat

Indications

The indications below including FDA-approved indication and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Rytelo is indicated for adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) 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 (ESAs).

Compendial Use[2]

Myelodysplastic syndromes (MDS)

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Myelodysplastic Syndromes (MDS)[1,2]

Authorization of 24 weeks may be granted for treatment of lower risk (e.g., International Prognostic Scoring System-Revised (IPSS-R) very low, low, and intermediate risk disease) myelodysplastic syndromes (MDS) with transfusion-dependent anemia when both of the following criteria are met:

- The member has not responded to, has lost response to, or is ineligible for erythropoiesis-stimulating agents (ESAs).
- The member has been receiving regular red blood cell (RBC) transfusions as defined by greater than or equal to 4 units per 8 weeks.

Continuation of Therapy

Authorization of 6 months may be granted for continued treatment in members requesting authorization for an indication listed in the coverage criteria section when both of the following criteria are met:

- The member has achieved or maintained a reduction in red blood cell transfusion burden.
- The member has not experienced an unacceptable toxicity from Rytelo.

References

1. Rytelo [package insert]. Foster City, CA: Geron Corporation; June 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 7, 2025.