CVS Caremark®

| 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 Indications1

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 Use2

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.