Imetelstat (Rytelo™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

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
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
Myelodysplastic syndromes (MDS)

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

COVERAGE CRITERIA

Myelodysplastic Syndromes (MDS)

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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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.

EFFECTIVE DATE 9/30/2025

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