

DRUG POLICY

Rytelo™ (imetelstat)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Rytelo (imetelstat) drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

For the treatment of adult members with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring four or more red blood cell (RBC) units over 8 weeks who have not responded to, have lost response to, or are ineligible for erythropoiesis-stimulating agents (ESAs).

Compendial Use

Myelodysplastic syndromes (MDS)

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Initial therapy requests:
 - A. Chart notes, medical records, or laboratory values demonstrating lack of response or lost response to erythropoiesis-stimulating agents (ESAs) or serum erythropoietin concentration for ineligibility (if applicable)
 - B. Chart notes or medical records documenting number of red blood cell transfusions within an 8 week period
2. Continuation of therapy requests:

- A. Chart notes or medical record documentation supporting reduction or maintenance of red blood cell transfusion burden

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. Hematologist
2. Oncologist
3. Other specialist with expertise in the diagnosis and management of myelodysplastic syndromes

Criteria for Initial Approval

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 all the following criteria are met:

1. The member is 18 years of age or older
2. The member has not responded to, has lost response to, or is ineligible for erythropoiesis-stimulating agents (ESAs). Note: ineligibility to ESAs is defined by a serum erythropoietin concentration >500 mU/mL
3. The member has been receiving regular red blood cell (RBC) transfusions as defined by ≥ 4 units RBC over an 8-week period
4. The member does not have del(5q) mutation status
5. The member has not responded to or has lost response to Reblozyl (luspatercept-aamt)
6. The member will not be using the requested medication in combination with Reblozyl
7. The dose of the requested medication will not exceed 7.1 mg/kg IV every 4 weeks

Continuation of Therapy

Myelodysplastic Syndromes (MDS)

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

1. The member has achieved or maintained a reduction in red blood cell transfusion burden.
2. The member has not experienced an unacceptable toxicity from Rytelo.
3. The member will not be using the requested medication in combination with Reblozyl
4. The dose of the requested medication will not exceed 7.1 mg/kg IV every 4 weeks

Other

Rytelo (imetelstat) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J0870 – Injection, imetelstat, 1 mg (effective 1/1/25)
- J3490 – Unclassified drugs
- J9999 – Not otherwise classified, antineoplastic drugs

- C9399 – Unclassified drugs

REFERENCES

- Rytelo [package insert]. Foster City, CA: Geron Corporation; June 2024.
- The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed January 14, 2026.

POLICY HISTORY

Policy #: 05.05.51

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