Clinical Policy: Imetelstat (Rytelo)

Reference Number: CP.PHAR.690
Effective Date: 09.01.24
Last Review Date: 08.24
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Imetelstat (Rytelo™) is an oligonucleotide telomerase inhibitor.

FDA Approved Indication(s)

Rytelo is indicated for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell (RBC) units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Rytelo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Myelodysplastic Syndromes (must meet all)**:**

1. Diagnosis of MDS with transfusion-dependent anemia;
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Age ≥ 18 years;
4. Member has low risk or intermediate-1 risk MDS disease as classified by IPSS (*see Appendix D*);
5. Documentation of at least 4 RBC units transfused over 8 weeks;
6. Member does not have del(5q) cytogenetic abnormality;
7. Member meets one of the following (a or b):
   a. Inadequate response to or ineligible for ESA therapy (e.g., epoetin alfa, darbepoetin, *see Appendix B*);
   b. One of the following (i or ii):
      i. Failure of Retacrit™, unless contraindicated or clinically significant adverse effects are experienced;
      **Prior authorization may be required for Retacrit*
      ii. If Retacrit is unavailable due to shortage, member must use Epogen®, unless contraindicated or clinically significant adverse effects are experienced;
      **Prior authorization may be required for Epogen*
8. Rytelo is not prescribed concurrently with Reblozyl®;
9. Request meets one of the following (a or b):*
   a. Dose does not exceed 7.1 mg/kg every 4 weeks;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet all)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Myelodysplastic Syndromes (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy as evidence by decrease of RBC transfusions requirement;
3. Rytelo is not prescribed concurrently with Reblozyl;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. Dose does not exceed 7.1 mg/kg every 4 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ESA: erythropoiesis-stimulating agent
FDA: Food and Drug Administration
IPSS: International Prognostic Scoring System
MDS: myelodysplastic syndrome
RBC: red blood cell

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Procrit®, Epogen®, Retacrit® (epoetin alfa)*	40,000 to 60,000 units SC 1 to 2 times per week every week	Target hemoglobin up to 12 g/dL
Aranesp® (darbepoetin alfa)*	150 to 300 mcg SC every other week	Target hemoglobin up to 12 g/dL

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: MDS Risk Classification

- International Prognostic Scoring System (IPSS) classification:

Risk Category	Risk Score
Low	0
Intermediate-1	0.5 – 1
Intermediate-2	1.5 – 2
High	2.5 – 3.5

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MDS	7.1 mg/kg intravenous infusion over 2 hours every 4 weeks	7.1 mg/kg/4 weeks

VI. Product Availability

Single-dose vials: 47 mg, 188 mg

VII. References

1. Rytelo Prescribing Information. Foster City, CA: Geron Corporation.; June 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217779s000lbl.pdf. Accessed June 17, 2024.
2. Bohlius J, Bohlke K, Castelli R, et al. American Society of Hematology/American Society of Clinical Oncology clinical practice guideline update: Management of Cancer-Associated Anemia with Erythropoiesis-Stimulating Agents. 2019 May 20; J Clin Oncol 37:1336-1351. Available at: https://ascopubs.org/doi/pdf/10.1200/JCO.18.02142.
3. Clinical Pharmacology [database online]. Elsevier, Inc.; 2024. Available at: https://www.clinicalkey.com/pharmacology/. Accessed June 18, 2024.
4. National Comprehensive Cancer Network. Myelodysplastic Syndromes Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed June 20, 2024.
5. Platzbecker U, Santini V, Fenaux P, et al. Imetelstat in patients with lower-risk myelodysplastic syndromes who have relapsed or are refractory to erythropoiesis-stimulating agents (IMerge): a multinational, randomized, double-blind, placebo-controlled, phase 3 trial. Lancet. 2024 Jan 20;403(10423):249-260. doi: 10.1016/S0140-6736(23)01724-5. Epub 2023 Dec 1. Erratum in: Lancet. 2024 Jan 20;403(10423):248. doi: 10.1016/S0140-6736(24)00057-6. PMID: 38048786.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0870	Injection, imetelstat, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	07.16.24	08.24
HCPCS code added [J0870] and removed codes [C9399, J9999].	11.07.24	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.