Medical Policy:

Rytelo (imetelstat) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.422	February 19, 2025	September 9, 2024

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Rytelo, an oligonucleotide telomerase inhibitor, is indicated for the treatment of low- to intermediate-1 risk myelodysplastic syndromes (MDS) in adults with transfusion-dependent anemia requiring ≥ 4 red blood cell (RBC) units over 8 weeks who have not responded to, or have lost response, or are ineligible for erythropoiesis-stimulating agents (ESAs).

Length of Authorization

Initial: Coverage will be provided for 6 months
Continuation: Coverage will be provided for 1 year

Dosing Limits [Medical Benefit]

The recommended dosage of Rytelo is 7.1 mg/kg given by a healthcare provider via intravenous

infusion over 2 hours once every 4 weeks.

Max Units (per dose and over time) [HCPCS Unit]:

• 940 mg every 4 weeks

Guideline

1. **Myelodysplastic Syndrome.** Approve if the patient meets ONE of the following (A **OR** B):

A. Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, iv, v, vi, **AND** vii):

i. Patient is ≥ 18 years of age; **AND**

ii. According to the prescriber, patient has low- to intermediate-1 risk myelodysplastic syndrome (MDS); **AND**

Note: MDS risk category is determined using the International Prognostic Scoring System (IPSS).

iii. Patient has transfusion-dependent anemia, defined as requiring transfusion of ≥ 4 red blood cell units over an 8-week period; **AND**

iv. According to the prescriber, patient has not responded, lost response to, or is ineligible for erythropoiesis-stimulating agents; **AND**

Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera).

v. Patient does NOT have deletion 5q [del(5q)] cytogenic abnormalities; **AND**

vi. Rytelo will NOT be used in combination with an erythropoiesis stimulating agent; **AND**

vii. The medication is being prescribed by or in consultation with an oncologist or hematologist; **OR**

B. Patient is Currently Receiving Rytelo. Approve for 1 year if, according to the prescriber, the patient has experienced a clinically meaningful decrease in transfusion burden.

Note: For a patient who has not received 6 months (24 weeks) of therapy or who is restarting therapy, refer to Initial Therapy criteria above.

Dosing. Approve up to 7.1 mg/kg by intravenous infusion administered not more frequently than once every 4 weeks.

Applicable Procedure Codes

Code	Description
J0870	Injection, imetelstat, 1 mg

Applicable NDCs

Code	Description
82959-0112-01	One 47-mg single-dose vial of Rytelo
82959-0111-01	One 188-mg single-dose vial of Rytelo

ICD-10 Diagnoses

Code	Description

D46.0	Refractory Anemia Without Ring Sideroblasts, So Stated
D46.1	Refractory Anemia With Ring Sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.4	Refractory Anemia, Unspecified
D46.9	Myelodysplastic Syndrome, Unspecified
D46.A	Refractory Cytopenia With Multilineage Dysplasia
D46.B	Refractory Cytopenia With Multilineage Dysplasia And Ring Sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
D46.Z	Other myelodysplastic syndromes

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/19/2025	Annual Review: added: D46.20, D46.21, D46.22, D46.C, and D46.Z, added dosing limits. No criteria changes.
EmblemHealth & ConnectiCare	9/9/2024	New Policy

References

1. Rytelo® intravenous infusion [prescribing information]. Foster City, CA: Geron; June 2024.