Medical Drug Clinical Criteria

Subject:	Rytelo (imetelstat)		
Document #:	CC-0266	**Publish Date:**	09/10/2024
Status:	New	**Last Review Date:**	08/16/2024

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Overview

This document addresses the use of Rytelo (imetelstat). Rytelo is an oligonucleotide telomerase inhibitor 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 units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA). Rytelo is administered by intravenous infusion only over a period of 2 hours.

Myelodysplastic syndromes (MDS) are conditions that can occur when the body no longer makes enough healthy, normal blood cells in the bone marrow. This leads to a low number of one or more types of blood cells. A shortage of red blood cells (anemia) is the most common finding. MDS is also known as a form of blood cancer. Several types of MDS exist, based on how many types of blood cells are affected along with other factors. About one-third of MDS patients can progress to a rapidly growing cancer of bone marrow cells called acute myeloid leukemia (AML). The World Health Organization (WHO) provides classifications for myeloid neoplasms and acute leukemias. It classifies MDS into 6 main types, primarily based on how the cells in the bone marrow look under the microscope. The goal of treatment in these patients focuses on symptom control, quality of life improvement, reduction or elimination of RBC transfusions and toxicity minimization.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Rytelo (imetelstat)

Requests for Rytelo (imetelstat) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis low to intermediate risk myelodysplastic syndromes (MDS); **AND**
III. Documentation is provided that individual is transfusion-dependent anemia requiring four (4) or more red blood cell units over eight (8) weeks in the last sixteen (16) weeks; **AND**
IV. Documentation is provided that individual is relapsed, refractory, or is ineligible for erythropoiesis-stimulating (ESA) agents

Continuation requests for Rytelo (imetelstat) may be approved if the following criteria are met:

I. Documentation is provided that individual demonstrates continued need for treatment and has confirmation of response to treatment as evidenced by a decrease in transfusion burden from baseline

Rytelo (imetelstat) for MDS may not be approved for the following:

I. Individual has not responded (response defined as decrease in transfusion burden from baseline) after 24 weeks of treatment (i.e. Administration of 6 doses consecutively) at maximum dose level (i.e. 7.1 mg/kg every 4 weeks); **OR**
II. Individual has hemoglobin higher than 12 g/dL (NCCN 2A); **OR**
III. When the above criteria are not met and for all other indications

Rytelo (imetelstat) may not be approved when the above criteria are not met and for all other indications.

Quantity Limits

Rytelo (imetelstat) Quantity Limits

Drug	Limit
Rytelo 47 mg, 188 mg vial	7.1 mg/kg per 4 weeks

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J0870	Injection, imetelstat, 1 mg [Rytelo]

ICD-10 Diagnosis

C93.10	Chronic myelomonocytic leukemia, not having achieved remission
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.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
D46.4	Refractory anemia, unspecified
D46.Z	Other myelodysplastic syndromes
D46.9	Myelodysplastic syndrome, unspecified

Document History

New: 08/16/2024
Document History:

- 08/16/2024 –Select Review: Create criteria for Rytelo. Coding Reviewed: Add HCPCS C9399 and J9999 for Rytelo. Add ICD-10-CM C93.10, D46.0, D46.1, D46.20, D46.21, D46.22, D46.A, D46.B, D46.C, D46.4, D46.Z, D46.9. Add HCPCS J0870 for Rytelo effective 1/1/2025 and delete HCPCS C9399 and J9999.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.

2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 12, 2024.
    a. Myelodysplastic Syndromes. Version 2.2024. Revised May 22, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.