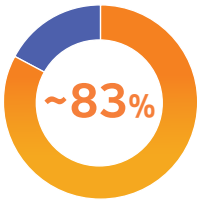
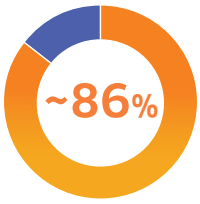
RYTELO® (imetelstat) for Injection 47 mg 188 mg

RYTELO is covered for the majority of patient lives[1]



Commercial lives covered



Medicare Advantage lives covered

As of February 2025.

Medicare comprises more than 90% of RYTELO's payer mix[1,a]

Medicare Fee-For-Service makes up the vast majority of the payer mix, with no prior authorization requirement.[1]

- Coverage is aligned to the Imetelstat (RYTELO) Prescribing Information and the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®).[2-4]

Medicare Advantage is the next largest payer and commercial comprises a small segment.[1]

- Prior authorization may be required.
- Medical policy criteria can vary and may be aligned to Imetelstat (RYTELO) Prescribing Information and/or NCCN Guidelines®.

This educational resource is informational only and not intended as reimbursement advice, legal advice, medical advice, or a substitute for a provider's independent professional judgment.

Geron and its agents make no guarantee regarding reimbursement for any service or item. It is the provider's sole responsibility to determine details specific to individual patients' insurance plans and should contact third-party payers for more specific information.

The information provided is not a guarantee of coverage. Actual benefits are determined by each plan administrator in accordance with its policies and procedures. Because formularies change and many health plans offer more than one formulary, please check with the health plan to confirm coverage for individual patients.

NCCN=National Comprehensive Cancer Network.

[a]Data from June 2024 to February 2025.[1]

INDICATION

RYTELO® (imetelstat) 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 units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Thrombocytopenia

RYTELO® can cause thrombocytopenia based on laboratory values. In the clinical trial, new or worsening Grade 3 or 4 decreased platelets occurred in 65% of patients with MDS treated with RYTELO.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.

Medical Exceptions

If a patient does not meet the plan's medical policy criteria for RYTELO, you may consider a medical exception. Some plans may accept a Letter of Medical Necessity to support the request. Consider reviewing the policy to identify which criteria the patient meets and which they do not. Check with the individual plan for more details.

It's generally best to tailor your request to the specific patient and point out the criteria that the patient meets and provide clinical rationale on why your patient should be exempted from any criteria they do not meet.

Consider including

- ☐ Background on the patient's diagnosis based on clinical diagnostic tests
- ☐ Clinical status and evidence of medication and RBC transfusion history
- ☐ Clinical justification supporting the choice of RYTELO, and a medical evaluation of potential disease progression if the patient does not receive treatment
- ☐ Any patient-specific reasons for treatment choice
- ☐ Quality of life considerations

Documentation that supports your request, which may include

- ☐ Medical and medication history, RBC transfusions, and lab results
- ☐ NCCN Guidelines or CMS-recognized compendia
- ☐ Prescribing Information for RYTELO
- ☐ RYTELO clinical publications
- ☐ Letter of approval from the FDA

CMS=Centers for Medicare and Medicaid Services; FDA=US Food and Drug Administration; RBC=red blood cell.

Refer to the **Sample Letter of Medical Necessity** for additional guidance.

Peer-to-Peer Discussions

If the prior authorization is denied for clinical reasons, you may be able to request a peer-to-peer discussion between the prescribing physician and the insurance plan. You may also request that the insurance plan's peer reviewer be of the same specialty (ie, hematology).

Consider gathering relevant information before the discussion, including

Patient and insurance information

- ☐ Name and date of birth of patient
- ☐ Primary insurance policy holder
- ☐ Insurance policy and group number

Drug information

- ☐ Prescribing Information for RYTELO
- ☐ NCCN Guidelines or CMS-recognized compendia

Patient characteristics

- ☐ Quality of life considerations

Clinical documentation

- ☐ Summary of patient's diagnosis
- ☐ Medical justification for prescribing RYTELO
- ☐ Details as to why RYTELO may be medically necessary for the patient
- ☐ Lab test results
- ☐ Medication history, including duration of therapy and side effects, if applicable
- ☐ RBC transfusion history, including frequency

It's ideal to clarify next steps before concluding the discussion:

- Note any required follow-up
- Confirm approval timing

REACH4RYTELO™

For more information regarding patient access, call REACH4RYTELO at **1-844-4RYTELO (1-844-479-8356)**, Monday through Friday, from 8:00 AM to 8:00 PM ET or email support@REACH4RYTELO.com.[a]

[a]All programs provided through REACH4RYTELO are subject to eligibility requirements. REACH4RYTELO and its agents make no guarantee regarding coverage and reimbursement for RYTELO. Geron reserves the right to modify or discontinue REACH4RYTELO at any time without notice.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Thombocytopenia (cont'd)

Monitor patients with thrombocytopenia for bleeding. Monitor complete blood cell counts prior to initiation of RYTELO, weekly for the first two cycles, prior to each cycle thereafter, and as clinically indicated. Administer platelet transfusions as appropriate. Delay the next cycle and resume at the same or reduced dose or discontinue as recommended.

Neutropenia

RYTELO can cause neutropenia based on laboratory values. In the clinical trial, new or worsening Grade 3 or 4 decreased neutrophils occurred in 72% of patients with MDS treated with RYTELO.

Monitor patients with Grade 3 or 4 neutropenia for infections, including sepsis. Monitor complete blood cell counts prior to initiation of RYTELO, weekly for the first two cycles, prior to each cycle thereafter, and as clinically indicated. Administer growth factors and anti-infective therapies for treatment or prophylaxis as appropriate. Delay the next cycle and resume at the same or reduced dose, or discontinue as recommended.

Infusion-Related Reactions

RYTELO can cause infusion-related reactions. In the clinical trial, infusion-related reactions occurred in 8% of patients with MDS treated with RYTELO; Grade 3 or 4 infusion-related reactions occurred in 1.7%, including hypertensive crisis (0.8%). The most common infusion-related reaction was headache (4.2%). Infusion-related reactions usually occur during or shortly after the end of the infusion.

Premedicate patients at least 30 minutes prior to infusion with diphenhydramine and hydrocortisone as recommended and monitor patients for at least one hour following the infusion as recommended. Manage symptoms of infusion-related reactions with supportive care and infusion interruptions, decrease infusion rate, or permanently discontinue as recommended.

Embryo-Fetal Toxicity

Based on animal findings, RYTELO can cause embryo-fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with RYTELO and for 1 week after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurred in 32% of patients who received RYTELO. Serious adverse reactions in >2% of patients included sepsis (4.2%), fracture (3.4%), cardiac failure (2.5%), and hemorrhage (2.5%). Fatal adverse reactions occurred in 0.8% of patients who received RYTELO, including sepsis (0.8%).

Most common adverse reactions (≥10% with a difference between arms of >5% compared to placebo), including laboratory abnormalities, were decreased platelets, decreased white blood cells, decreased neutrophils, increased AST, increased alkaline phosphatase, increased ALT, fatigue, prolonged partial thromboplastin time, arthralgia/myalgia, COVID-19 infections, and headache.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.

References: 1. Data on File. Geron Corporation. **2.** RYTELO (imetelstat) [prescribing information]. Foster City, CA. Geron Corp.; 2024. **3.** Centers for Medicare & Medicaid Services. Medicare benefit policy manual, Chapter 15, Section 50.4.5: Compendia as authoritative sources for use in the determination of a "medically accepted indication" of drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen. Transmittal 96. Pub 100-02. October 24, 2008. Accessed May 27, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r96bp.pdf **4**. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes V.2.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed April 11, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use, or application, and disclaims any responsibility for their application or use in any way.

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