



# BILLING AND CODING

This resource is provided for informational purposes only. It is always the provider's responsibility to determine details specific to individual patients and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules. Geron and its agents make no guarantee regarding reimbursement for any service or item. **This resource is not intended as reimbursement advice, legal advice, medical advice, or a substitute for a provider's independent professional judgment.**

## 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.

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.

**Please see additional Important Safety Information throughout and [full Prescribing Information](#), including [Medication Guide](#).**

# Submitting Claims for RYTELO

Once a patient has received their prescribed treatment with RYTELO, your practice or facility may submit a claim to the patient's insurance plan(s). Submitting timely and accurate claims can help facilitate prompt coverage and reimbursement. To help avoid coverage denials and underpayment, it is important to review claims before submitting.

## Example steps for claim submission

- **Confirm payer requirements**, including coverage and PA requirements, coding and billing guidelines, and any supplemental medical documentation.
- **Check the claim for accuracy and completeness**, including patient and provider information, coding, billing units, and any additional information required by the payer (eg, PA approval number [Item 23 on CMS-1500, FL 50 on CMS-1450], tax identification number, and/or NDC).
- **Confirm compliance with claim submission rules**, including required standards for electronic claims, character limit requirements, and time frame for submitting claims.



Coding and documentation requirements for medications may be confirmed with each payer before submitting a claim for coverage and reimbursement.

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For reimbursement support related to a specific patient, please contact REACH4RYTELO at **1-844-4RYTELO (1-844-479-8356)**, Monday through Friday, from 8:00 AM to 8:00 PM ET.<sup>a</sup>

CMS=Centers for Medicare and Medicaid Services; FL=form locator; NDC=National Drug Code; PA=prior authorization.

<sup>a</sup>All programs provided through REACH4RYTELO are subject to eligibility requirements. Geron reserves the right to modify or discontinue REACH4RYTELO at any time without notice.

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 **RYTELO**<sup>TM</sup>  
(imetelstat) for Injection 47 mg  
188 mg

# Product Package Codes

National Drug Codes<sup>1</sup>

Coding System	10-Digit Code	11-Digit Code <sup>a</sup>	Description
NDC	NDC 82959-112-01	NDC <b>82959-0112-01</b>	One RYTELO 47-mg single-dose vial
	NDC 82959-111-01	NDC <b>82959-0111-01</b>	One RYTELO 188-mg single-dose vial

Guidelines for reporting the NDC in the appropriate format, quantity, and unit of measure (UN) vary by state and by payer and should be reviewed prior to submitting a claim.



It is important to identify and use the correct codes for each patient. Providers are responsible for all coding decisions. Geron does not guarantee coverage or reimbursement.

FDA=US Food and Drug Administration; HIPAA=Health Insurance Portability and Accountability Act; IV=intravenous.  
<sup>a</sup>The 11-digit NDC is the HIPAA-approved standard.

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# Drug Administration Codes

## Product Administration—IV Infusion

One unit of the CPT® code may be used to report the time from the start of an infusion until 60 minutes into the infusion.<sup>2</sup>

### Commonly Used Administration Codes<sup>2</sup>

Coding System	Code and Description	
CPT®	<b>Injection and intravenous infusion chemotherapy and other highly complex drug or highly complex biologic agent administration:</b>	
	96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
	96415	Chemotherapy administration, intravenous infusion technique, each additional hour, single or initial substance (list separately in addition to code 96413 for initial hour of infusion services) <sup>a</sup>
	<b>Therapeutic, prophylactic, or diagnostic administration:</b>	
	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour
	96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis; each additional hour <sup>a</sup>



**IMPORTANT:** When documenting the start and stop time for the medication infusion, do not include any time when the IV is running to keep the line open.

These codes are provided for education only. Each provider is responsible for all coding decisions and submitting complete and accurate information to the patient's insurance plan. The use of these codes does not guarantee coverage or reimbursement.

CPT®=Current Procedural Terminology.

<sup>a</sup>Used for each additional hour of chemotherapy administration by IV infusion, or for infusion intervals greater than 30 minutes beyond the first hour.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

#### 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.

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# Healthcare Common Procedure Coding System (HCPCS)



**IMPORTANT:** J0870: Permanent J-code for RYTELO effective for dates of service on or after January 1, 2025

## RYTELO Permanent J-Code<sup>3,a</sup>

Code	Description	Sites of Care
J0870	Injection, imetelstat, 1 mg	All

### Billing Units

11-Digit NDC	Vial Size	Billing Units
82959-0112-01	One (1) 47-mg single-dose vial	47 billing units
82959-0111-01	One (1) 188-mg single-dose vial	188 billing units

SP=specialty pharmacy.

<sup>a</sup>If RYTELO is supplied through an SP, you will not need to submit a claim for reimbursement for the product; however, you may decide it is appropriate to submit a claim for reimbursement for services associated with RYTELO.



**IMPORTANT:** If RYTELO is administered on or after January 1, 2025, the permanent J-code replaces the miscellaneous J-code.

- ☐ Be sure to bill according to the amount of RYTELO administered or wasted when using the permanent J-code (1 unit per 1 mg). Keep in mind that CMS does not use fractional billing units; unit should be rounded up to the nearest whole number.
- ☐ When using the permanent J-code J0870, Item 19 on the CMS-1500 and FL 80 on the CMS-1450 are no longer required to be populated.
- ☐ Update your billing software to reflect the permanent J-code J0870, units: 1 unit per 1 mg, and expected reimbursement.
- ☐ During the benefits verification process, confirm that the permanent J-code J0870 has been added to the health plan's system to help with the adjudication process.
- ☐ Understand your payer contracts and how they may be adjusted by the permanent J-code J0870.
- ☐ Review claims to verify that they are processed correctly according to the permanent J-code J0870.
- ☐ Please check with respective payer to understand if the prior authorization needs to be resubmitted or revalidated.

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(imetelstat) for Injection <sup>47 mg</sup>  
<sup>188 mg</sup>

# Diagnosis Codes

## Example ICD-10-CM Diagnosis Codes<sup>4</sup>

Coding System	Code	Description
ICD-10-CM	D46.0	Refractory anemia without ring sideroblasts
	D46.1	Refractory anemia with ring sideroblasts
	D46.A	Refractory cytopenia with multilineage dysplasia
	D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
	D46.4	Refractory anemia, unspecified
	D46.Z	Other myelodysplastic syndromes
	D46.9	Myelodysplastic syndrome, unspecified



The codes provided above are only examples. Each provider is responsible for all coding decisions, including responsibility for submission of complete and accurate information. Diagnosis codes used in submission of claims should be chosen based on the individual patient's medical diagnosis. Coding information provided does not provide a guarantee of reimbursement.

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

#### 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 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.

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## Place of Service Codes

Commonly Used Place of Service Codes<sup>5</sup>

Code	Location	Description
11	Office	Location, other than a hospital, skilled nursing facility, military treatment facility, community health center, state or local public health clinic, or intermediate care facility, where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
19	Off campus: outpatient hospital	A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
22	On campus: outpatient hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

The codes provided above are only examples. Each provider is responsible for all coding decisions, including responsibility for submission of complete and accurate information. Place of service codes used in submission of claims should be chosen based on location that RYTELO was administered for each individual patient. Coding information provided does not provide a guarantee of reimbursement.

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# Hospital Outpatient Billing

## Example Revenue Codes<sup>6</sup>

Coding System	Code	Description
AHA Revenue System	0250	Pharmacy general classification
	0260	IV infusion
	0335	Chemotherapy administration - IV
	0510	Outpatient clinic
	0636 <sup>a</sup>	Drugs requiring detailed coding



Revenue code requirements for claims with a CPT code for IV infusion may vary.  
**Please check with the payer for a complete list of applicable codes.**

The codes provided above are only examples. Each provider is responsible for all coding decisions, including responsibility for submission of complete and accurate information. Coding information provided does not provide a guarantee of reimbursement.

AHA=American Hospital Association.

<sup>a</sup>For Medicare, revenue code 0636 must be used in conjunction with a drug HCPCS code. Private payers may also require revenue code 0636.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

#### Embryo-Fetal Toxicity

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.

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# Wastage Coding

**RYTELO is packaged as a single-dose vial. Some payers, including Medicare, will pay for drug waste on single-use items when medically necessary and appropriately documented**

The JW modifier is used on claims to report the amount of drug discarded that is eligible for payment under the discarded drug policy.<sup>7</sup>

- When a portion of a drug in a single-use vial is discarded, the medical record must document the amount administered and the amount wasted.<sup>7</sup>
- Carefully review the definition of discarded drug provided in the relevant policy to ensure accuracy of claim submission.
- Medicare requires discarded drugs to be reported with the JW modifier on a separate line from the amount administered.

The JZ modifier is used on claims to report that no amount of drug was discarded.<sup>7</sup>

- Some payers require the use of the JZ modifier for claims involving single-dose vials with no discarded amounts.
- If the use of the JZ modifier is required, and there is no waste, RYTELO must be billed on one line with modifier JZ.



For additional information on use of JW and JZ modifiers, CMS has developed a [\*\*Frequently Asked Questions resource\*\*](#).

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# Sample CMS-1500 Claim Form

The below is provided only as an example.

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## Medicare FFS Claim Example

**Item 21 [EMC = Loop 2300, HI, 01-2 (or Diagnosis 1)]:** Enter the appropriate ICD-10-CM diagnosis code as documented in the patient's medical record. An example code for this drug is **D46.0** Refractory anemia without ring sideroblasts.

**Item 23 (EMC = Loop 2300 or 2400, REF/G1, 02):** Enter the PA approval number, if required by insurance.

**Item 24A (EMC = Loop 2400, DTP/472, 03):**

**Nonshaded area:** Place the actual date of service.

**Shaded area:** Depending on payer requirements, enter the N4 indicator first, followed by the 11-digit NDC. Then, list the unit measurement code (UN), and, last, the quantity (1 unit = 1 vial). Each NDC should be listed as its own line item.

**Item 24B (EMC = Loop 2300 or 2400, CLM, 05 or SV1, 05):** Enter the appropriate place of service code.

**Item 24D (EMC = Loop 2400, SV1, 01-2):** Enter the appropriate HCPCS code, J0870, Injection, imetelstat, 1 mg. RYTELO is packaged as a single-dose vial. Some payers, including Medicare, require drug waste to be reported with the JW modifier on a separate line from the amount administered. If there is not waste, RYTELO Injection should be billed on one line with modifier JZ; please check if payer requires JZ and JW modifiers. For administration, enter the appropriate code or codes for the infusion duration. As an example, a 60-minute infusion of chemotherapy requires 96413.

**Item 24E (EMC = Loop 2400, SV1, 07-1):** Specify the diagnosis letter that corresponds with the primary diagnosis related to the drug and drug administration code(s).

**Item 24F (EMC = Loop 2400, SV1, 02):** Enter the charge for each listed service.

Complete sections F-J.

**Item 24G [EMC = Loop 2400, SV1, 04 (03=UN)]:** Enter the number of service units for each item.

Please check with the patient's insurance plan(s) for their specific guidelines for billing and coding.

EMC=electronic media claim; FFS=Fee-for-Service.

## IMPORTANT SAFETY INFORMATION (cont'd)

### 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%).

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**Sample CMS-1450/UB-04**  
**Claim Form**  
**Medicare Claim Example Outpatient**

The below is provided only as an example.

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**FL 42 (EMC = Loop 2400, SV201):**

List the appropriate revenue code for the drug. Match the descriptor for RYTELO Injection to your revenue code 0636. Additionally, enter an appropriate revenue code for the administration service, 0335 for **chemotherapy administration: IV**, or others based on the cost center at which the service was performed.

**FL 43:** Enter the description of the procedure for the Revenue Code billed. Depending on payer requirements, enter a detailed drug description: the N4 indicator first, followed by the 11-digit NDC. In the third place, list the unit measurement code, and, last, the quantity.

**FL 44 [EMC = Loop 2400, SV202-2 (SV202-1=HC/HP)]:** Enter the appropriate HCPCS code, **J0870, Injection, imetelstat, 1 mg**. RYTELO is packaged as a single-dose vial. Some payers, including Medicare, require drug waste to be reported with the JW modifier on a separate line from the amount administered. If there is no waste, RYTELO Injection should be billed on one line with modifier JZ; please check if payer requires JZ and JW modifiers.

For administration, enter the appropriate code(s) for the infusion duration. As an example, a 60-minute infusion of chemotherapy requires 96413.

**FL 46 (EMC = Loop 2400, SV205):** Enter the units for the HCPCS code billed. Enter the number of service units for each item.

**FL 56 (EMC = Loop 2010AA, NM1/85/09):** Indicate the appropriate NPI number.

**FL 67A-Q [EMC = Loop 2300, HI01-2 (HI01-1=BK)]:** Enter a diagnosis code for the drug documented in the medical record. Be as specific as possible. The code listed here is an example: **D46.0 Refractory anemia without ring sideroblasts.**

1		2		3a FILL CMTL 4 DATE 1		4 TYPE OF BILL	
8 PATIENT NAME a				9 PATIENT ADDRESS b			
10 BIRTHDATE				11 SEX			
12 DATE				13 ADMISSION 13 100 14 TYPE 15 SMC 16 DHR			
17 ETAT				18 CONDITION CODES 20 22 23 24 25 26 27 28 29 30 31 32			
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193		194		195			



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## **IMPORTANT SAFETY INFORMATION** (cont'd)

## ADVERSE REACTIONS (cont'd)

Most common adverse reactions ( $\geq 10\%$  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.

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**RYTELO™**  
(imeteIstat) for Injection 47 mg  
188 mg

# Important Safety Information

## WARNINGS AND PRECAUTIONS

### Thrombocytopenia

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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

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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 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

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%).

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**Please see [full Prescribing Information](#), including [Medication Guide](#).**

**References:** 1. RYTELO. Prescribing information. Geron Corp.; 2024. 2. American Medical Association. 2024 CPT Professional Edition. Current Procedural Terminology (CPT®) copyright 2023 by the American Medical Association. All rights reserved. Chicago, IL: AMA; 2023. 3. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) application summaries and coding recommendations. Centers for Medicare & Medicaid Services. Published October 2, 2024. Accessed October 4, 2024. <https://www.cms.gov/files/document/2024-hcpcs-application-summary-quarter-3-2024-drugs-and-biologicals-posted-10-02-2024.pdf> 4. Myelodysplastic syndromes D46. ICD10Data.com website. Accessed September 26, 2024. <https://www.icd10data.com/ICD10CM/Codes/C00-D49/D37-D48/> 5. Place of service code set. CMS.gov website. Updated May 2, 2024. Accessed September 26, 2024. <https://www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets> 6. Understanding hospital revenue codes. Value Healthcare Services website. Accessed September 26, 2024. <https://valuehealthcareservices.com/education/understanding-hospital-revenue-codes/> 7. Discarded drugs and biologicals – JW modifier and JZ modifier policy frequently asked questions. Centers for Medicare and Medicaid Services website. Accessed September 26, 2024. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf>



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All other trademarks are the property of their respective owners.

The RYTELO logo features a stylized flame icon to the left of the word "RYTELO" in a bold, uppercase, sans-serif font. Below "RYTELO" is the text "(imelstat) for Injection" in a smaller font, with "47 mg" and "188 mg" to the right.