# RYTELO™

(imetelstat) for Injection 47 mg 188 mg

# 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 [Box 23 on CMS-1500, Box 50 on CMS-1450], tax identification number, and/or NDC number).
- **Confirm compliance with claim submission rules**, including required standards for electronic claims, character limit requirements, and time frame for submitting claims.

**NOTE**

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

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**REACH4RYTELO™**

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.[a]

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

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

## 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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# Product Package Codes

### NDC Codes[1]

| Coding System | 10-Digit Code | 11-Digit Code | Description | Location on CMS-1500 Payer Form | Location on CMS-1450/UB-04 Form |
|---|---|---|---|---|---|
| NDC | NDC 82959-112-01 | NDC 82959-**0**112-01 | RYTELO for IV infusion 47-mg vial | Box 19 and Box 24A | Box 80 |
| | NDC 82959-111-01 | NDC 82959-**0**111-01 | RYTELO for IV infusion 188-mg vial | | |

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

> **NOTE**
>
> 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; IV=intravenous.

## 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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# Drug Administration Codes

## Product Administration—IV Infusion

One unit of code 96413 or 96365 may be used to report the time from the start of an infusion until 60 minutes into the infusion.[2] The total number of hours (from when the medication starts dripping until it stops) is reported in Box 24G.

### Commonly Used Administration Codes[2]

| Coding System | Code and Description | | Location on CMS-1500 Payer Form | Location on CMS-1450/UB-04 Form |
|---|---|---|---|---|
| CPT® | Chemotherapy and other highly complex drug or biologic agent administration: | | Box 24D | Box 44 |
| | 96413 | Intravenous infusion up to 60 minutes, single or initial substance/drug | | |
| | 96415 | 61 minutes or more (use with 96413) | | |

**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.

## 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.

#### 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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# Healthcare Common Procedure Coding System (HCPCS)

HCPCS Codes[3,4,a]

| Coding System | Code | Description | Location on CMS-1500 Payer Form | Location on CMS-1450/UB-04 Form | Comments |
|---|---|---|---|---|---|
| HCPCS | J3490 | Unclassified drugs | Box 24D | NA | When completing the CMS-1500 form, use Box 19 to include details about product dosing, such as drug name, NDC number, and number of units. In the case of a Medicare hospital outpatient claim, you may be required to use a miscellaneous C-code rather than a J-code. |
| | J9999 | Not otherwise classified, antineoplastic drugs | | | |
| | C9399 | Unclassified drugs | NA | Box 44 | |

### Billing Units for Commercial/Medicare Advantage

| 1 unit = 1 mg | 47-mg vial | 47 units |
|---|---|---|
| | 188-mg vial | 188 units |

### Billing Units for Medicare

| Billing Units = 1 |
|---|

RYTELO is designated by a miscellaneous J-code (also referred to as an unclassified J-code or NOC J-code) or a miscellaneous C-code. J3490 is more commonly used than J9999. Miscellaneous C-codes are utilized in the hospital setting. The miscellaneous code should be used until a permanent code is assigned.

For commercial and Medicare Advantage claims with an NOC claim form, payers typically require supplemental product information for manual claims processing, such as the medication name, 11-digit NDC number, concentration, amount administered, and route of administration; however, specific requirements may vary by payer and should be reviewed prior to submitting a claim.[5]

For Medicare, miscellaneous HCPCS codes should be billed with a service unit of 1 and claims with miscellaneous codes must include additional information, such as the name of the drug, NDC, and dosage administered. This additional information is reported in Item 19 of the CMS-1500 claim form or Locator 80 of the UB-04/CMS-1450 claim form.

[a]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.

NOC=not otherwise classified; SP=specialty pharmacy.

## IMPORTANT SAFETY INFORMATION (cont'd)

### ADVERSE REACTIONS (cont'd)

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.

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# Diagnosis Codes

<div align="center">Example <em>ICD-10-CM</em> Diagnosis Codes[6]</div>

| Coding System | Code | Description | Location on CMS-1500 Payer Form | Location on CMS-1450/UB-04 Form |
|---|---|---|---|---|
| ICD-10-CM | D46.0 | Refractory anemia without ring sideroblasts | Box 21 | Box 67 |
| | 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 | | |
| | D46.9 | Myelodysplastic syndrome, unspecified | | |

**NOTE**

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

### 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.

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# Place of Service Codes

## Commonly Used Place of Service Codes[7]

| Coding | 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 of 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. |
| 21 | Inpatient hospital | A facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians to patients admitted for a variety of medical conditions. |
| 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.**

## 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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# Hospital Outpatient Billing

## Example Revenue Codes

### Administration Codes[8]

| Coding System | Code | Description | Location on CMS-1450/UB-04 Form |
|---|---|---|---|
| AHA Revenue System | 0250 | Pharmacy general classification | Box 42[b] |
| | 0636[a] | Drugs requiring detailed coding | |
| | 0260 | IV infusion | |
| | 0510 | Outpatient clinic | |

**NOTE**
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.

[a]For Medicare, revenue code 0636 must be used in conjunction with HCPCS code 96413. Private payers may also require revenue code 0636.

[b]The appropriate revenue code should be entered into Box 42 of the CMS-1450/UB-04 claim form.

AHA=American Hospital Association.

## 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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**RYTELO™**
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# Sample CMS-1500 Claim Form

> The below is provided only as an example.
>
> Each provider is responsible for all coding decisions, including responsibility for submission of complete and accurate information. Example coding information provided does not provide a guarantee of reimbursement.

## Medicare Claim Example

**Box 19**: Provide the name of the medication (RYTELO), the route of administration (IV), and the amount administered in units (eg, mg). Many payers may also require the 11-digit NDC number.

**Box 21**: Enter the appropriate *ICD-10-CM* code(s) based on clinical diagnosis.

**Box 23**: Enter the PA approval number, if required by insurance.

**Box 24A**:

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

**Shaded area**: Depending on payer requirements, include an N4 indicator, the NDC number, the name of medication and vial size, the dispensing unit of measure qualifier (eg, mL), and the number of units (up to 3 decimal places) in the shaded portion of this box. Each NDC should be listed as its own line item.

**Box 24B**: Indicate the administration place of service code.

**Box 24D**: Indicate administration HCPCS code, CPT code, and modifiers for products and services. If there is no discarded drug from a vial, enter JZ after the HCPCS code. If there is wastage, enter JW. Please refer to your payer's policy for more information.

**Box 24E**: Enter the form-provided reference letter from Box 21 that corresponds to the diagnosis for which the product or procedure is being billed.

**Box 24F**: Indicate the price you are requesting for the service.

Complete sections F-J.

**Please check with the patient's insurance plan(s) for their specific guidelines for billing and coding NOC codes as they may vary.**

MAC=Medicare Administrative Contractor.

**Box 24G**: Medicare MACs require only 1 unit placed here and the total administered amount (mg) to be placed within Box 19. Please note that the units of measure requirement for NOC codes can vary by payer, region, state, etc.

*(Form fields shown in example: Box 19: "RYTELO, IV admin, XX mg administered, 82959011101, 82959011201"; Box 21: "D46.0"; service lines:)*

| Line | Shaded / Service | Place of Service | HCPCS | Modifier | Diagnosis Pointer | Units |
|---|---|---|---|---|---|---|
| 1 | N482959011201ML[XX] | 11 | J3590 | JZ | A | 1 |
| 2 | N482959011101ML[XX] | 11 | J3590 | JZ | A | 1 |
| 3 | Chemo IV infusion 1 hour | 11 | 96413 | | A | 1 |
| 4 | Chemo IV infusion add'l hour | 11 | 96415 | | A | 1 |

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## 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.

**Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.**
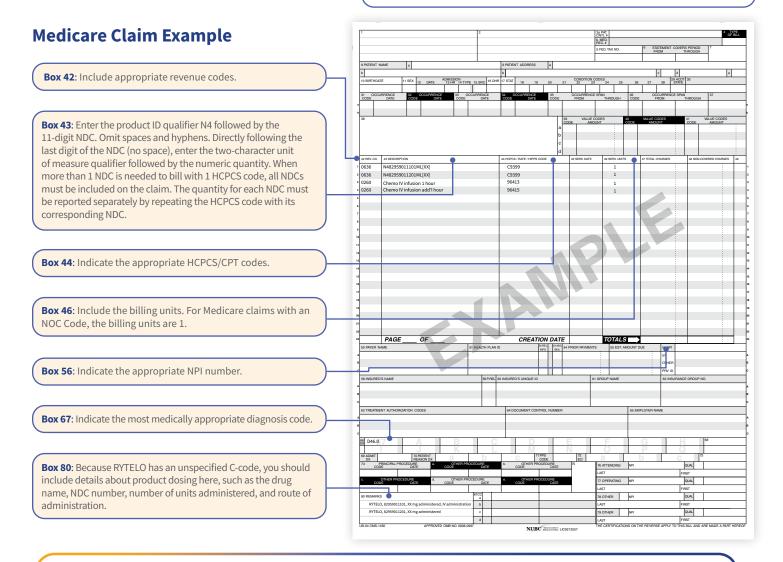
**RYTELO™**
(imetelstat) for Injection 47 mg / 188 mg

# Sample CMS-1450/UB-04 Claim Form

The below is provided only as an example.

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## Medicare Claim Example

**Box 42**: Include appropriate revenue codes.

**Box 43**: Enter the product ID qualifier N4 followed by the 11-digit NDC. Omit spaces and hyphens. Directly following the last digit of the NDC (no space), enter the two-character unit of measure qualifier followed by the numeric quantity. When more than 1 NDC is needed to bill with 1 HCPCS code, all NDCs must be included on the claim. The quantity for each NDC must be reported separately by repeating the HCPCS code with its corresponding NDC.

**Box 44**: Indicate the appropriate HCPCS/CPT codes.

**Box 46**: Include the billing units. For Medicare claims with an NOC Code, the billing units are 1.

**Box 56**: Indicate the appropriate NPI number.

**Box 67**: Indicate the most medically appropriate diagnosis code.

**Box 80**: Because RYTELO has an unspecified C-code, you should include details about product dosing here, such as the drug name, NDC number, number of units administered, and route of administration.



Form fields visible:

| 42 REV. CD. | 43 DESCRIPTION | 44 HCPCS / RATE / HIPPS CODE | 46 SERV. UNITS |
|---|---|---|---|
| 0636 | N482959011101ML[XX] | C9399 | 1 |
| 0636 | N482959011201ML[XX] | C9399 | 1 |
| 0260 | Chemo IV infusion 1 hour | 96413 | 1 |
| 0260 | Chemo IV infusion add'l hour | 96415 | 1 |

67 DX: D46.0

80 REMARKS:
RYTELO, 82959011101, XX mg administered, IV administration
RYTELO, 82959011201, XX mg administered

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## 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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# Important Safety Information

**WARNINGS AND PRECAUTIONS**

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**Neutropenia**

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**Infusion-Related Reactions**

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**ADVERSE REACTIONS**

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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 full Prescribing Information, including Medication Guide.**

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# References

**1.** RYTELO (imetelstat) [prescribing information]. Foster City, CA. 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.** HCPCS J-Codes. HCPCS.codes website. Accessed June 7, 2024. https://hcpcs.codes/j-codes/ **4.** HCPCS Code C9399. HCPCS.codes website. Accessed June 7, 2024. https://hcpcs.codes/c-codes/C9399/ **5.** Centers for Medicare and Medicaid Services. Medicare claims processing manual: chapter 26. Revised December 14, 2023. **6.** Myelodysplastic syndromes D46. ICD10Data.com website. Accessed June 7, 2024. https://www.icd10data.com/ICD10CM/Codes/C00-D49/D37-D48/ **7.** Place of service code set. CMS.gov website. Accessed June 7, 2024. https://www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets **8.** Understanding hospital revenue codes. Value Healthcare Services website. Accessed June 7, 2024. https://valuehealthcareservices.com/education/understanding-hospital-revenue-codes/