



Rytelo
Rytelo (imetelstat) J0870
Prior Authorization Request
Medicare Part B Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

- Type 2 Diabetes Mellitus**
- Patient has confirmed diagnosis of type 2 diabetes mellitus
 - Patient has inadequate glycemic control (HbA1c ≥7.0%) on current therapy
 - Patient has tried and failed, intolerant, or has contraindication to metformin
 - Patient is not on insulin therapy as sole agent (may be used in combination)
 - eGFR ≥30 mL/min/1.73m²
 - Prescribed by or in consultation with endocrinologist or primary care provider experienced in diabetes management

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

Patient had an **adequate response** or **significant improvement** while on this medication.

Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Rytelo Prior Authorization

Drug Name(s):

RYTELO

IMETELSTAT

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan, in accordance with the Label.
 - Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Rytelo

- Anemia, After failure, lost response, or ineligibility for erythropoiesis-stimulating agents, requiring 4 or more RBC units over 8 weeks - Myelodysplastic syndrome, Low- to intermediate-1-risk disease

Off-Label Uses:

N/A

Age Restrictions:

- Safety and effectiveness in pediatric patients have not been established

Other Clinical Consideration:

N/A

Resources:

https://www.micromedexolutions.com/micromedex2/librarian/CS/35C32A/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/5043B7/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=934416&contentSetId=100&title=Imetelstat&servicesTitle=Imetelstat&brandName=Rytelo&UserMdxSearchTerm=rytelo#