SAMPLE LETTER OF MEDICAL NECESSITY

Please note that the following letter is intended only as a SAMPLE Letter of Medical Necessity that suggests information a payer may request from a prescriber to document a patient's medical necessity for treatment in order to obtain coverage for a requested therapy. The prescriber must use their independent medical judgment to decide what information to incorporate regarding their patient's specific needs and medical history. In addition, health plan requirements may vary, so the prescriber should refer to the prior authorization or coverage information specific to their patient's health plan before completing a Letter of Medical Necessity. Please note that some payers may have specific forms that must be completed to request prior authorization or to document medical necessity.

Use of this template or the information in this template does not guarantee reimbursement or coverage.

REMEMBER:

Anything in red should be deleted and replaced with your responses if applicable. If the red text does not apply, delete the sentence. Before sending this letter to your insurance carrier/ Case Manager, **DELETE THIS INSTRUCTIONS SECTION.** Your letter should start with the date and should be on your practice's letterhead.

LETTER OF MEDICAL NECESSITY SHOULD BE ON THE PROVIDER'S LETTERHEAD

[Date]
[Health Plan Name]
ATTN: [Department]
[Medical/Pharmacy Director Name]
[Health Plan Address]
[City, State Zip]

Name: [Patient's Name]
DOB: [XX/XX/XXXX]
Patient Policy ID Number: [Policy ID #]
Reference Number: [Reference #]
Date(s) of Service: [XX/XX/XXXX]

Re: Letter of Medical Necessity for REBLOZYL® (luspatercept-aamt)

Dear [Medical/Pharmacy Director Name],

I am writing to request authorization for the use of REBLOZYL® (luspatercept-aamt) for my patient, [Patient Name]. REBLOZYL® has been FDA approved for the first line treatment of LR-MDS-associated anemia. This letter provides the rationale and relevant information about the patient's medical history.

Summary of Patient's Medical History:

[Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition. It is your responsibility to determine the requirements for each insurance carrier.]

[You may want to briefly describe the patient's diagnosis and relevant medical and transfusion history, including outcomes and challenges]

[Patient Name] has been diagnosed with MDS-associated anemia and requires initiation of first-line therapy. [Patient Name] has a hemoglobin level of ___ and *[If applicable]* [RBC transfusion history].

Rationale for REBLOZYL® (luspatercept-aamt) Therapy:

REBLOZYL® (luspatercept-aamt) is a clinically appropriate treatment for [Patient Name] that is FDA approved for the first line treatment of LR-MDS-associated anemia. In addition, REBLOZYL® is medically necessary for [Patient Name] due to the following factors: [include reasons for medical necessity based on patient circumstances; use your independent clinical decision-making to determine the appropriate content to include to support your professional opinion that your patient is a good candidate for treatment with REBLOZYL®].

[In the instance the patient has MDS-associated anemia and requires a transfusion but has not received regular blood transfusions, you may want to consider including the following language]

REBLOZYL® (luspatercept-aamt) has an FDA-approved first-line indication for the treatment of anemia without previous ESA use in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions[1]. [Patient Name] requires administration of REBLOZYL® without a concurrent blood transfusion due to [you may want to include reasons for medical necessity based on patient-specific circumstances].

[In the instance the patient has MDS-associated anemia and the patient is RS negative status and Reblozyl would be the first line treatment, you may want to consider including the following language]

REBLOZYL® (luspatercept-aamt) has an FDA-approved first-line indication for the treatment of anemia without previous ESA use in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions[1]. This indication applies irrespective of ring sideroblast (RS) status. [Patient Name] requires administration of REBLOZYL® irrespective of RS status due to [you may want to include reasons for medical necessity based on patient circumstances].

Conclusion:

Given the FDA approval of REBLOZYL® (luspatercept-aamt) and the rationale provided above, I believe this treatment is medically necessary for [Patient Name]. I request that you approve coverage for REBLOZYL® as a covered benefit.

[You may want to include:]

Please find enclosed supporting documentation, including:

- [Relevant clinical notes and history]

- [Transfusion logs/ lab history (hgb)]

- [Weight/dosing documentation]

- [Treatment plan and anticipated outcomes]

- [Relevant publications/references, e.g., the REBLOZYL Package Insert or NCCN Guidelines...]

If you require any additional information, please do not hesitate to contact me directly at [Your Phone Number] or [Your Email Address]. Thank you for your timely attention to this request.

Sincerely,

[Your Name, Title]

[Your Practice/Facility Name]

[Your Contact Information]

Enclosures:

[List all enclosed supporting materials]

References

1. REBLOZYL US Prescribing Information. Summit, NJ: Celgene Corp; 2026

If you would like additional published references to support your payer outreach letter, please contact BMS Medical Information at medical.communications@bms.com or 1-800-321-1335.