

LETTER OF MEDICAL NECESSITY TEMPLATE

Some payers may require that the prescribing physician document a patient's medical necessity for the treatment to secure insurance approval. The following letter, provided by Gamida Cell Inc., is intended as an optional TEMPLATE Letter of Medical Necessity that outlines the information a payer may request. Health plan requirements may vary. Prescribers should refer to the prior authorization or coverage information specific to their patient's health plan before completing a Letter of Medical Necessity. Use of this template does not guarantee coverage or reimbursement for the drug. The editable letter on Page 2 includes text in brackets that needs to be replaced with the relevant patient and other information. When submitting the Letter of Medical Necessity, all brackets should be deleted, and your office letterhead should be added.

Please refer to the full Prescribing Information for details on all FDA-approved indications and any additional questions regarding OMISIRGE® (omidubicel-only). It is the sole responsibility of the healthcare provider to include the proper information and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

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[Physician's Letterhead]

[Date]

[Name of Payer Contact]

[Contact Title]

[Name of Health Insurance]

[Company][Address]

[City, State, ZIP Code]

RE: Letter of Medical Necessity for Coverage of OMISIRGE® (omidubicel-only)

Patient: [Patient Name], **Date of Birth:** [Date]

Diagnosis: [Diagnosis]

Group Number: [Number]

Policy Number: [Number]

Policyholder: [Policyholder Name]

Dear [Payer Contact Name]:

I am writing on behalf of my patient, [Patient Name], to document the medical necessity for OMISIRGE as part of their treatment for [Diagnosis].

[Prescribing physician to choose which indication to populate below:

OMISIRGE was approved by the US Food and Drug Administration on April 17, 2023 for patients with hematologic malignancies in need of an allogeneic hematopoietic cell transplant (allo-HCT). See prescribing information for full indication at [omisirge.com](https://www.omisirge.com).

OR

OMISIRGE was approved by the US Food and Drug Administration on [December 10, 2025] for use in patients with severe aplastic anemia. See prescribing information for full indication at [omisirge.com](https://www.omisirge.com).]

This letter serves to document my patient's medical history and diagnosis and to summarize my treatment rationale for OMISIRGE in patients with [hematologic malignancies needing an allo-HCT] [severe aplastic anemia], and document why this drug is necessary.

Summary of Patient's Medical History and Diagnosis

[Patient Name] is [Age] years old and was initially diagnosed with [Diagnosis] on [Date]. [PatientName] has been in my care since [Date].

[Provide a summary of the patient's medical history and diagnosis including, among other relevant information, the patient's clinical history, current symptoms and condition, any potential contraindications, and any relevant laboratory test results, highlighting the factors leading you to recommend OMISIRGE. Potentially important details may include information on donor source availability and any previous IST treatment or intolerance to therapy].

Rationale for Treatment

[Include your clinical rationale and reasons for ordering OMISIRGE]

In summary, using OMISIRGE is medically necessary and reasonable as part of treating [Patient Name's] [Diagnosis], and I ask you to please consider coverage of OMISIRGE on [Patient Name's] behalf. Please refer to the enclosed supporting documents for further details, and do not hesitate to call me at [Phone Number] if you have any questions or if you require additional information.

Please refer to the [\[List any Enclosures\]](#) enclosed with this letter.

Thank you for your attention on this matter.

Sincerely,

[\[Prescribing Physician Name and Credentials\]](#)[\[NPI Number\]](#)

Enclosures: [\[List any Enclosures, such as: Prescribing Information, Clinical Notes and Records\]](#)