

Appeal Letter for Coverage of OMISIRGE® (omidubicel-only)

[Date]

[Insurance Company Name]

[Address]

Subject: Appeal for Coverage of OMISIRGE® (omidubicel-only) for [Patient Name], [Policy Number]

Dear [Medical Director or Appeals Department],

I am writing to formally appeal the denial of coverage for **OMISIRGE® (omidubicel-only)** for my patient, [Patient Name], who is diagnosed with [specific hematologic malignancy (eg, acute myeloid leukemia)] [severe aplastic anemia] and requires an **allogeneic hematopoietic stem cell transplant (HSCT)**.

Clinical Background

[Patient Name] is a [age]-year-old [male/female] with [diagnosis] for whom HSCT is medically necessary. No suitable matched donor is available. OMISIRGE, an FDA-approved, nicotinamide-modified allogeneic hematopoietic progenitor cell therapy derived from umbilical cord blood, is indicated for use in adults and pediatric patients aged 12 years and older with hematologic malignancies following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection and for use in adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning.

Medical Necessity and Evidence

OMISIRGE significantly reduces time to neutrophil recovery and infection risk compared with standard cord blood transplantation, as demonstrated in pivotal clinical trials. This improvement is critical for [Patient Name] given their high risk of infection and complications. [add additional comments from the patient's medical record as applicable pertaining to the patient's medical condition and need for OMISIRGE as the donor source option of choice]

FDA Approval and Guidelines

- **FDA Indication:** OMISIRGE is approved for use in adults and pediatric patients aged 12 years and older with hematologic malignancies following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection, and for use in adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning
- **NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®):** Supports the use of Omidubicel to shorten time to engraftment and reduce the risk of infections compared to umbilical cord blood

Request

Given the urgency and medical necessity, I respectfully request that [Insurance Company Name] reconsider coverage for OMISIRGE under the medical benefit. Denial of this therapy places [Patient Name] at significant risk of prolonged neutropenia, infection, and mortality.

Supporting Documentation

- Clinical notes and transplant plan
- FDA approval letter
- Peer-reviewed literature supporting OMISIRGE efficacy and safety

Please contact me at [Phone Number] or [Email] for any additional information. Thank you for your prompt attention to this appeal.

Sincerely,

[Your Name, Credentials]

[Title/Organization]

[Contact Information]

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