

OMISIRGE CODING REFERENCE

OMISIRGE is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for¹:

- use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection
- use in adults and pediatric patients 6 years and older with severe aplastic anemia following reduced intensity conditioning

This summary sheet provides general coding and billing information for OMISIRGE. Depending on the patient's payer and the site of care where OMISIRGE is administered, different code types and codes may be utilized on claims. The code sets included in this guide are generally required to be used by payers per HIPAA. Check with each payer for their specific requirements.

The coding information provided in this document is intended for informational and reference purposes only. The information provided in this guide should not be construed as medical or legal advice and is not a guarantee of coverage or reimbursement. Coding and coverage policies are subject to change. It is the responsibility of the provider to determine coverage and appropriate coding for a particular patient.

For additional information, contact Gamida Cell at [\(844\) 477-7478](tel:8444777478) or see [OMISIRGE Full Prescribing Information](#).

HIPAA, Health Insurance Portability and Accountability Act.

INDICATIONS AND USAGE

OMISIRGE is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for the treatment of:

- Adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.
- Adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning.

IMPORTANT SAFETY INFORMATION

WARNING: GRAFT VERSUS HOST DISEASE, INFUSION REACTIONS, AUTOIMMUNE CYTOPENIAS, GRAFT FAILURE, and ENGRAFTMENT SYNDROME

- Graft-vs-Host Disease (GvHD): GvHD may be fatal. Administration of immunosuppressive therapy may decrease the risk of GvHD
- Infusion reactions: Infusion reactions may be fatal. Monitor patients during infusion and discontinue for severe reactions. Use is contraindicated in patients with known allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material
- Autoimmune cytopenias: Autoimmune cytopenias have occurred following treatment of severe aplastic anemia. Monitor blood counts prior to and after infusion. Manage cytopenias according to local institutional guidelines
- Graft failure: Graft failure may be fatal. Monitor patients for laboratory evidence of hematopoietic recovery
- Engraftment syndrome: Engraftment syndrome may be fatal. Treat engraftment syndrome promptly with corticosteroids

Please see Important Safety Information throughout and full [Prescribing Information](#), including Boxed Warning.

Diagnosis Coding²

OMISIRGE is used to treat numerous hematologic malignancies and other hematologic conditions. There is no specific diagnosis code to reflect severe aplastic anemia; therefore, accurate ICD-10-CM code selection must be based on documentation in the patient's medical record and represent coding to the highest level of specificity, which includes the type, sites of disease, and clinical status.

Code	Code Description
D61.1	Drug-induced aplastic anemia
D61.2	Aplastic anemia due to other external agents
D61.3	Idiopathic aplastic anemia
D61.89	Other specified aplastic anemias and other bone marrow failure syndromes
D61.9	Aplastic anemia, unspecified

IMPORTANT SAFETY INFORMATION (Cont'd)

CONTRAINDICATIONS

OMISIRGE is contraindicated in patients with known hypersensitivity to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material.

WARNINGS AND PRECAUTIONS

Graft-versus-Host Disease

Acute and chronic graft-versus-host disease (GvHD) have occurred following treatment with OMISIRGE. Acute GvHD manifests as maculopapular rash, gastrointestinal symptoms, and elevated bilirubin. Chronic GvHD manifests as skin rash, oral symptoms, ocular dryness, transaminase elevations, gastrointestinal symptoms, or serositis. Patients treated with OMISIRGE should receive immunosuppressive drugs to decrease the risk of GvHD, and be monitored for signs and symptoms of GvHD, and treated if GvHD develops.

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Procedure Coding

ICD-10-PCS procedure codes are used on claims for all payers to report services provided during an inpatient stay. The ICD-10-PCS codes below should be reported for the infusion of OMISIRGE. Medicare has mapped these codes to MS-DRG 014 – Allogeneic bone marrow transplant.³ For Medicare-specific claims billing guidance for allogeneic stem cell transplant, refer to the *Medicare Claims Processing Manual, Chapter 3, Section 90.3.1.A*.⁴

Code	Code Description
XW133C8	Transfusion of Omidubicel into Peripheral Vein, Percutaneous Approach, New Technology Group 8
XW143C8	Transfusion of Omidubicel into Central Vein, Percutaneous Approach, New Technology Group 8

Current Procedural Terminology (CPT®) codes in the table below may be applicable for professional billing for services associated with providing OMISIRGE.

Code	Code Description
38204	Management of recipient hematopoietic cell donor search and cell acquisition
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity and Infusion-Related Reactions

Hypersensitivity and infusion-related reactions have occurred with OMISIRGE administration. Serious hypersensitivity reactions, including anaphylaxis, may be due to DMSO, residual gentamicin, Dextran 40, human serum albumin (HSA), and bovine material in OMISIRGE. OMISIRGE may contain residual antibiotics if the cord blood donor was exposed to antibiotics in utero. Patients with a history of allergic reactions to antibiotics should be monitored for allergic reactions following OMISIRGE administration.

Signs and symptoms of hypersensitivity reactions may include bronchospasm, wheezing, angioedema, pruritus, hives, fever, and hypotension during or after OMISIRGE infusion. Infusion-related reactions may begin within minutes of the start of infusion of OMISIRGE, although symptoms may continue to intensify and not peak for several hours after the completion of the infusion.

Premedicate patients with antipyretics, histamine antagonists, and corticosteroids and monitor closely for signs and symptoms of hypersensitivity and infusion-related reactions. When a reaction occurs, pause the infusion and institute supportive care as needed.

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Product Coding

HCPCS Level II codes specific to OMISIRGE have not yet been assigned. OMISIRGE may be reported using an unclassified/miscellaneous HCPCS code.⁵ When reporting one of these codes, additional information may be required for billing, such as the product name, NDC, dosage administered, and route of administration.

Code	Code Description
C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs
J3590	Unclassified biologics

NDCs may have varying reporting requirements. The NDC for OMISIRGE is included here in an example of the 11-digit format.

Qualifier	11-Digit NDC	Quantity Qualifier	Claim Form Format
N4	73441-0800-04	UN	N473441080004UN

HCPCS, healthcare common procedure coding system; NDC, national drug code.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS

Autoimmune Cytopenias

Autoimmune cytopenias (AICs) have occurred with OMISIRGE administration in patients with SAA. AIC is characterized by thrombocytopenia, anemia, and neutropenia, alone or in combination, occurring weeks to months post-transplant, often after initial hematopoietic recovery. Risk factors for post-transplant AIC include younger age, ATG-containing conditioning, underlying SAA, and delayed T cell chimerism. Monitor blood counts prior to and after OMISIRGE infusion. Manage cytopenias according to local institutional guidelines.

Graft Failure

Graft failure has occurred with OMISIRGE administration. Primary graft failure, which may be fatal, is defined as failure to achieve an absolute neutrophil count greater than 500 per microliter blood by Day 42 after transplantation. Immunologic rejection is the primary cause of graft failure. Patients should be monitored for laboratory evidence of hematopoietic recovery.

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Revenue Coding

Revenue codes must follow the standards set by the National Uniform Billing Committee (NUBC). Revenue code 0815 should be reported on claims for all payers for allogeneic hematopoietic stem cell donor search and cell acquisition services, per NUBC requirements.⁵ Charges for the procedure to infuse OMISIRGE should be reported with the revenue code designed by the NUBC for the department from which the expense was incurred.

Code	Code Description
0815	Allogeneic Stem Cell Acquisition/Donor Services
0940	Other therapeutic services - General

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS

Malignancies of Donor Origin

Malignancy of donor origin, including post-transplant lymphoproliferative disorder (PTLD), has occurred with OMISIRGE administration. PTLD manifests as a lymphoma-like disease favoring non-nodal sites. PTLD is usually fatal if not treated. The etiology is thought to be donor lymphoid cells transformed by Epstein-Barr virus (EBV). Serial monitoring of blood for EBV DNA may be warranted in patients with persistent cytopenias. A donor-cell derived myelodysplastic syndrome (MDS) has occurred with OMISIRGE administration. The natural history is presumed to be the same as that for de novo MDS. Monitor life-long for secondary malignancies. In the event that a secondary malignancy occurs, contact Gamida Cell at (844) 477-7478.

Engraftment Syndrome

Engraftment syndrome may occur because OMISIRGE is derived from umbilical cord blood. Monitor patients for unexplained fever, rash, hypoxemia, weight gain, and pulmonary infiltrates in the peri-engraftment period. Treat with corticosteroids as soon as engraftment syndrome is recognized to ameliorate symptoms. If untreated, engraftment syndrome may progress to multiorgan failure and death.

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Value And Condition Coding

Value codes may be relevant on claims for OMISIRGE. Value code 88 is used on an allogeneic hematopoietic stem cell transplant recipient's claim to report the total number of related donors that were evaluated for the transplant. In the case of an unrelated donor source, such as OMISIRGE, if there were no related donors evaluated for the recipient, "0" is appropriate to report, but if related donors were evaluated and ruled out, use the correct number of donors evaluated to report the numbers of donors assessed for value code 88. Value code 89 is used on the transplant recipient's claim to report the total donor acquisition charges for the allogeneic stem cell transplant episode (including charges submitted on separate claims).

Code	Code Description
88	Allogeneic stem cell transplant – number of related donors evaluated
89	Allogeneic stem cell transplant – total all-inclusive donor charges

Condition codes may be relevant on claims for OMISIRGE. For commercial payers that accept claims for donor search and cell acquisition services prior to the transplant, the NUBC created condition code 88 to report donor charges.

Code	Code Description
88	Allogeneic stem cell transplant related donor charges

IMPORTANT SAFETY INFORMATION (Cont'd)

Transmission of Serious Infections

Transmission of infectious disease may occur because OMISIRGE is derived from umbilical cord blood. Disease may be caused by known or unknown infectious agents. Donors are screened for increased risk of infection with human immunodeficiency virus (HIV), human T-cell lymphotropic virus (HTLV), hepatitis B virus (HBV), hepatitis C virus (HCV), T pallidum, West Nile virus (WNV), transmissible spongiform encephalopathy (TSE) agents, vaccinia, and Zika virus [for umbilical cord blood (UCB) collected between March 2016 and 20 May 2024]. Donors are also screened for clinical evidence of sepsis and communicable disease risks associated with xenotransplantation. Maternal blood samples are tested for HIV types 1 and 2, HTLV types I and II, HBV, HCV, T pallidum, and WNV. OMISIRGE is tested for sterility, endotoxin, and mycoplasma. There may be an effect on the reliability of the sterility test results if the cord blood donor was exposed to antibiotics in utero. These measures do not totally eliminate the risk of transmitting these or other transmissible infectious diseases and disease agents. Testing of maternal and infant donor blood is also performed for evidence of donor infection due to cytomegalovirus (CMV).

Please see Important Safety Information throughout and full [Prescribing Information](#), including Boxed Warning.

References

1. Omisirge (prescribing information).
2. ICD-10-CM Tabular list of diseases and injuries.
https://ftp.cdc.gov/pub/health_statistics/nchs/publications/ICD10CM/2022/icd10cm-tabular-2022-April-1.pdf
3. https://www.cms.gov/icd10m/FY2023-version40.1-fullcode-cms/fullcode_cms/P0042.html
4. Medicare claims processing manual, Chapter 3, Section 90.3.1.A.2;
<https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c03.pdf>
5. <https://www.astct.org/Education/Coverage-Coding-Billing/HCT-Coding-and-Billing-Resources>

IMPORTANT SAFETY INFORMATION (Cont'd)

Test results may be found on the container label and/or in accompanying records.

Product manufacturing includes bovine-derived reagents. While all animal-derived reagents are tested for animal viruses, bacteria, fungi, and mycoplasma before use, these measures do not eliminate the risk of transmitting these or other transmissible infectious diseases and disease agents. Final sterility test results may not be available at the time of use, but Quality Assurance (QA) will communicate any positive results from sterility testing to the physician. Report the occurrence of transmitted infection to Gamida Cell at (844) 477-7478.

Transmission of Rare Genetic Diseases

OMISIRGE may transmit rare genetic diseases involving the hematopoietic system because it is derived from umbilical cord blood. Cord blood donors have been screened to exclude donors with sickle cell anemia, and anemias due to abnormalities in hemoglobins C, D, and E. Because of the age of the donor at the time cord blood collection takes place, the ability to exclude rare genetic diseases is severely limited. Report the occurrence of transmitted rare genetic disease to Gamida Cell at (844) 477-7478.

ADVERSE REACTIONS

Hematological malignancies: The most common adverse reactions (incidence > 20%) are infections, GvHD, and infusion and hypersensitivity reactions.

SAA: The most common adverse reactions (incidence > 20%) are infections, hyperglycemia, skin rash, febrile neutropenia, immune thrombocytopenia, acute kidney injury, acute GvHD, hypertension, hypoxia, and infusion related reactions.

Please see Important Safety Information throughout and full [Prescribing Information](#), including Boxed Warning.

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