Organ and Tissue Transplants

Policy Number: MCS096.06
Approval Date: March 13, 2024

Instructions for Use

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Related Policies
None

Coverage Guidelines

Human organ and tissue transplants, including pre-and post-operative medical, surgical, hospital services, and medically necessary ambulance transportation are covered when Medicare coverage criteria are met.

Notes:
- The guidelines in this Coverage Summary are for specific procedures only. For procedures not addressed in this Coverage Summary, refer to the Medicare Coverage Database to search for applicable coverage policies (National Coverage Determination, Local Coverage Determinations and Local Coverage Articles).
- All transplant procedures, including ventricular assist devices, for UnitedHealthcare Medicare Advantage Plan members must be performed by Optum Transplant Network facility and/or Medicare-Approved Transplant facility**.**
- A list of organ transplant facilities eligible for Medicare reimbursement is available at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Transplant-Laws-and-Regulations.html. (Accessed February 12, 2024)

Kidney, Pancreas, and Kidney-Pancreas Transplants

Kidney, pancreas and kidney-pancreas transplants are covered when criteria are met.

Refer to the:
- NCD for Pancreas Transplants (260.3).
- Medicare Benefit Policy Manual, Chapter 11 End Stage Renal Disease (ESRD), §140 - Transplantation.

Note: When the medical evaluation for a transplant is performed on the recipient or the living donor during the same inpatient stay in which the actual transplant occurs, all such services will be billed, and the costs will be accumulated in the normal manner. For example, all hospital services rendered to the donor will be considered kidney acquisition services. However, all physicians' services rendered to the living donor and all hospital and physicians' services rendered to the recipient will be billed

in the same manner as any other inpatient services on the account of the recipient. Refer to the Medicare Benefit Policy Manual, Chapter 11, §140.8 - Kidney Recipient Admitted for Transplantation and Evaluation.
(Accessed February 12, 2024)

Stem Cell Transplantation and Bone Marrow Transplantation

Allogeneic hematopoietic stem cell transplantation (HSCT) and autologous stem cell transplantation (AuSCT) are covered when criteria are met. Refer to the NCD for Stem Cell Transplantation (Formerly 110.8.1) (110.23).
(Accessed February 12, 2024)

Notes:

- Effective for services performed on or after August 4, 2010, allogeneic HSCT for myelodysplastic syndromes (MDS) is covered by Medicare pursuant to Coverage with Evidence Development (CED) in the context of a Medicare-approved, prospective clinical study.
  - Effective for services performed on or after January 27, 2016, allogeneic HSCT for multiple myeloma (MM), myelofibrosis (MF), and sickle cell disease (SCD) is covered by Medicare pursuant to Coverage with Evidence Development (CED) in the context of a Medicare-approved, prospective clinical study.
  - Refer to the NCD for Stem Cell Transplantation (Formerly 110.8.1) (110.23).
  - The list of Medicare approved clinical trials is available at http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/allo-HSCT.html.
  - For payment rules for NCDs requiring CED, refer to the Medicare Managed Care Manual, Chapter 4, §10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED).
- Acquisition charges for stem cell transplants apply only to allogeneic transplants, for which stem cells are obtained from a donor (other than the recipient himself or herself). Acquisition charges do not apply to autologous transplants (transplanted stem cells are obtained from the recipient himself or herself), because autologous transplants involve services provided to the beneficiary only (and not to a donor), for which the hospital may bill and receive payment. Refer to the Medicare Claims Processing Manual, Chapter 4, §231.11 - Billing for Allogeneic Stem Cell Transplants.

(Accessed February 12, 2024)

Islet Cell Transplantation in the Context of a Clinical Trial

Transplantation of partial pancreatic tissue or islet cells is not covered by UnitedHealthcare.

Notes:

- Members may have coverage by Medicare in a Medicare certified Clinical Trials. Effective October 1, 2004, as a result of section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Medicare will cover pancreatic islet cell transplantation for patients with Type I diabetes who are participating in National Institutes of Health-sponsored clinical trials.
  - Because this legislative change in benefits meets the significant cost threshold described in section 1852(a)(5) of the Social Security Act, MA organizations are not required to assume risk for the costs of this service until payments /can be appropriately adjusted to take into account the cost of this legislative change in benefits. As is the case for other qualifying clinical trial services, CMS will make payments directly to providers of covered islet cell transplant clinical trial services on a fee-for-service basis.
  - For detailed information, refer to the NCD for Islet Cell Transplantation in the Context of a Clinical Trial (260.3.1).
- CMS Payment Guidelines: CMS will make payment directly on a fee-for service basis for the routine costs of pancreatic islet cell transplants as well as transplantation and appropriate related items and services, for MA beneficiaries participating in an NIH-sponsored clinical trial. MA organizations will not be liable for payment for routine costs of this new clinical trial until MA payments can be appropriately adjusted to take into account the cost of this national coverage decision. Medicare contractors shall make payment on behalf of MA organizations directly to providers of these islet cell transplants in accordance with Medicare payment rules, except that beneficiaries are not responsible for the Part A and Part B deductibles. MA members will be liable for any applicable coinsurance amounts MA organizations have in place for clinical trial benefits. Refer to the Medicare Claims Processing Manual, Chapter 32, §70.5 - Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries.

(Accessed February 12, 2024)

Immunosuppressive Drugs

Post-transplant, immunosuppressive drug therapy following a Medicare covered organ transplant is covered. Refer to the Coverage Summary titled Medications/Drugs (Outpatient/Part B) for detailed coverage guideline.

Solid Organ Acquisition

Solid organ acquisition from cadaver or live donor is covered. Refer to the Medicare Benefit Policy Manual, Chapter 11 End Stage Renal Disease (ESRD), §140 – Transplantation. (Accessed February 12, 2024)

Transportation, Food, and Housing

Transportation, food and housing expense of the member and one escort may be covered. Refer to the member's EOC/SOB to determine coverage eligibility.

Note: Although not described in the EOC for UnitedHealthcare MedicareDirect plans, if the member is sent outside of the member's community for a transplant, UnitedHealthcare will arrange or pay for appropriate lodging and transportation costs for the member and a companion. This applies to all Medicare Advantage plans.

Umbilical Cord Blood Harvesting and Storage for Future Use

Medicare does not have a National Coverage Determination (NCD) for umbilical cord blood harvesting and storage for future use. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.

For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy titled Umbilical Cord Blood Harvesting and Storage for Future Use.

Note: After searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.
(Accessed February 12, 2024)

Policy History/Revision Information

Date	Summary of Changes
03/13/2024	• Routine review; no change to coverage guidelines • Archived previous policy version MCS096.05

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The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing the items or services in this coverage summary have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, UnitedHealthcare applies internal

coverage criteria in the UnitedHealthcare commercial policies referenced in this coverage summary. The coverage criteria in these commercial policies was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.