## Coverage Summary

### Transplants: Organ and Tissue Transplants

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<th>Policy Number:</th>
<th>Products: UnitedHealthcare Medicare Advantage Plans</th>
<th>Original Approval Date:</th>
<th>Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee</th>
<th>Last Review Date: 09/18/2018</th>
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**Related Medicare Advantage Policy Guidelines:**

- Adult Liver Transplantation (NCD 260.1)
- Dental Examination Prior to Kidney Transplantation (NCD 260.6)
- Heart Transplants (NCD 260.9)
- Heartbreath Test for Heart Transplant Rejection (NCD 260.10)
- Histocompatibility Testing (NCD 190.1)
- Intestinal and Multi-Visceral Transplantation (NCD 260.5)
- Islet Cell Transplantation in the Context of a Clinical Trial (NCD 260.3.1)
- Pancreas Transplants (NCD 260.3)
- Pediatric Liver Transplantation (NCD 260.2)
- Stem Cell Transplantation (Formerly 110.8.1) (NCD 110.23)
- Thoracic Duct Drainage (TDD) in Renal Transplants (NCD 20.3)

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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 is required where applicable.*

*There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence* (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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**INDEX TO COVERAGE SUMMARY**

I. COVERAGE

1. Covered transplants include but are not limited to:
   
   - a. Heart and Heart Lung Transplants
   - b. Kidney, Kidney-Pancreas, Pancreas Transplants
   - c. Adult Liver Transplants
   - d. Pediatric Liver Transplants
   - e. Intestinal and Multi-Visceral Transplantation
   - f. Stem Cell Transplantation and Bone Marrow Transplantation

2. Islet Cell Transplantation in the Context of a Clinical Trial

3. Immunosuppressive Drugs

4. Transplant related services include but are not limited to:
   
   - a. Dental/Oral examination
   - b. Thoracic Duct Drainage
   - c. Histocompatibility testing (HLA typing)
I. COVERAGE

Coverage Statement: 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:
- 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.

Guidelines/Notes:
1. Covered transplants include but are not limited to:
   a. Heart and heart-lung transplants are covered when criteria are met. See the NCD for Heart Transplants (260.9). (Accessed September 10, 2018)
      For artificial heart implants, see the Coverage Summary for Ventricular Assist Device (VAD) and Artificial Heart.
   b. Kidney, pancreas and kidney-pancreas transplants are covered when criteria are met. See the NCD for Pancreas Transplantation (260.3). Also see the Medicare Benefit Policy Manual, Chapter 11 End Stage Renal Disease (ESRD), §140 - Transplantation. (Accessed September 10, 2018)
      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. See the Medicare Benefit Policy Manual, Chapter 11, §140.8 - Kidney Recipient Admitted for Transplantation and Evaluation. (Accessed September 10, 2018)
   c. Adult liver transplants are covered when criteria are met. See the NCD for Adult Liver Transplantation (260.1). (Accessed September 10, 2018)
   d. Pediatric liver transplants are covered when criteria are met. See the NCD for Pediatric Liver Transplantation (260.2). (Accessed September 10, 2018)
e. Intestinal and Multi-Visceral Transplantation **are covered** when criteria are met. 

f. Stem cell transplantation and bone marrow transplantation **are covered** when criteria are met. See the [NCD for STEM CELL Transplantation Formerly 110.8.1 (110.23)](http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/allo-HSCT.html). (Accessed September 10, 2018)

### Allogeneic Hematopoietic Stem Cell Transplant (HSCT) for Myelodysplastic Syndromes (MDS):

Effective for services performed on or after August 4, 2010, allogeneic HSCT for MDS is covered by Medicare pursuant to Coverage with Evidence Development (CED) in the context of a Medicare-approved, prospective clinical study. 


### Allogeneic Hematopoietic Stem Cell Transplant (HSCT) for Multiple Myeloma (MM), Myelofibrosis (MF), and Sickle Cell Disease (SCD):

Effective for services performed on or after January 27, 2016, allogeneic HSCT for MM, MF and SCD is covered by Medicare pursuant to Coverage with Evidence Development (CED) in the context of a Medicare-approved, prospective clinical study.


**Note:** 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. See the [Medicare Claims Processing Manual, Chapter 4, §231.11 - Billing for Allogeneic Stem Cell Transplants](http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/allo-HSCT.html). (Accessed September 10, 2018)

For payment rules for NCDs requiring CED, see the [Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials](http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/allo-HSCT.html).

2. **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, see the NCD for Islet Cell Transplantation in the Context of a Clinical Trial (260.3.1) (Accessed September 10, 2018)

- 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. See the Medicare Claims Processing Manual, Chapter 32, §70.5 - Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries. (Accessed September 10, 2018)

3. **Immunosuppressive Drugs**

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

4. **Transplant related services include, but are not limited to:**

   a. Dental/oral examination performed on an inpatient basis prior to a kidney transplant is covered when criteria are met. See the NCD for Dental Examination Prior to Kidney Transplantation (260.6). (Accessed September 10, 2018)

   b. Thoracic duct drainage (TDD) is covered when used in renal transplantation. See the NCD for Thoracic Duct Drainage in Renal Transplantation (20.3). (Accessed September 10, 2018)

   c. Histocompatibility testing (HLA typing) for the transplant recipient and donor when the intended transplant recipient is a UnitedHealthcare Medicare member is covered when criteria are met. See the NCD for Histocompatibility Testing (190.1). (Accessed September 10, 2018)

   d. Solid organ acquisition from cadaver or live donor is covered. See the Medicare Benefit Policy Manual, Chapter 11 End Stage Renal Disease (ESRD), §140 – Transplantation. (Accessed September 10, 2018)

   e. 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**
f. Heartsbreath test for heart transplant rejection is **not covered**; see the NCD for Heartsbreath Test for Heart Transplant Rejection (260.10). (Accessed September 10, 2018)

g. Umbilical cord blood harvesting and storage for future use **is not covered**.
   - 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 for Umbilical Cord Blood Harvesting and Storage for Future Use. (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policy.)
   - Committee approval date: September 18, 2018
   - Accessed September 10, 2018

II. DEFINITIONS

III. REFERENCES

IV. REVISION HISTORY

04/01/2019
- Updated policy introduction; added language to clarify:
  - There are instances where [the Coverage Summary] may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG)
  - In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5)
- Retitled reference link that directs users to UnitedHealthcare Commercial policy

09/18/2018
Annual review; no updates.

09/19/2017
Annual review with the following recommended update - replaced the following note:

*All transplant procedures including Ventricular Assist Devices for UnitedHealthcare MedicareComplete members must be performed by a UnitedHealthcare MedicareComplete Preferred Transplant Network facility. This does not apply to UnitedHealthcare MedicareDirect members. UnitedHealthcare MedicareDirect members must have transplant procedures including Ventricular Assist Devices and Left Ventricular Assist Devices preformed in a Medicare Certified Transplant Facility.*

with the following:

*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.

09/20/2016  Annual review with the following updates:

Guideline 1.f (Stem Cell Transplant)
- Updated CMS reference from NCD for Stem Cell Transplantation (110.8.1) to NCD for STEM CELL Transplantation Formerly 110.8.1 (110.23) throughout the guideline.
- Replaced CMS reference from the “CMS Decision Memo for Stem Cell Transplantation (Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease) (CAG-00444R) at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=280” to the NCD for STEM CELL Transplantation Formerly 110.8.1 (110.23) - Under the Allogeneic Hematopoietic Stem Cell Transplant (HSCT) for Multiple Myeloma (MM), Myelofibrosis (MF), and Sickle Cell Disease (SCD) section of the guideline.

02/16/2016  Guideline 1.f (Stem Cell Transplant) – Added the following language:

“Allogeneic Hematopoietic Stem Cell Transplant (HSCT) for Multiple Myeloma (MM), Myelofibrosis (MF), and Sickle Cell Disease (SCD):
Effective for services performed on or after January 27, 2016, allogeneic HSCT for MM, MF and SCD is covered by Medicare pursuant to Coverage with Evidence Development (CED) in the context of a Medicare-approved, prospective clinical study.

10/20/2015  Annual review; no updates.

08/18/2015  Guideline 3 (Immunosuppressive Drugs)
- Revised coverage statement to read:
  Post-transplant, immunosuppressive drug therapy following a Medicare covered organ transplant is covered.
- Added reference link to the Coverage Summary for Medications/Drugs (Outpatient/Part B) for detailed coverage guideline.
- Deleted the detailed guideline for immunosuppressive drugs and moved to the Medications/Drugs (Outpatient/Part B).

04/21/2015  Guideline #1.f (Stem cell transplantation and bone marrow transplantation)
- Added CED NCD information pertaining to Allogeneic Hematopoietic Stem Cell Transplant (HSCT) for Myelodysplastic Syndromes (MDS),
- Added reference link to the list of Medicare approved clinical trials.
- Added reference link to the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials for payment rules for NCDs requiring CED.

12/16/2014  Annual review with the following updates:
- Reorganized policy content.
- Guideline 1.a (Heart and Heart-Lung Transplants) - Added the following to indicate:
For artificial heart implants, see the Coverage Summary for Ventricular Assist Device (VAD) and Artificial Heart

- Guideline 1.f (Stem Cell Transplantation and Bone Marrow Transplantation) - Updated the reference link to Medicare Claims Processing Manual, Chapter 4, Section 231.11-Billing for Allogeneic Stem Cell Transplants
- Guideline 2 (Islet Cell Transplantation in the Context of a Clinical Trial) - Added reference link to the Medicare Claims Processing Manual, Chapter 32, Section 70.5 - Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries.
- Guideline 3 (Immunosuppressive Drugs)
  - Move the following definitions from the Definition section:
    - Immunosuppressive drugs
    - Therapeutic regimen
  - Added reference link to the Coverage Summary for Medications/Drugs (Outpatient/Part B)
- Guideline 4.d (Solid organ acquisition from cadaver or live donor) - Added reference link to the Medicare Benefit Policy Manual, Chapter 11 End Stage Renal Disease (ESRD), § 140 – Transplantation
- Guideline 4.h (Artificial heart implants) - Removed; now addressed in Guideline 1
- Guideline 4.i (Storage costs of any organ or bone marrow) - Removed; no CMS reference available
- Guideline 4.j (Non-human organ transplantation) - Removed; no CMS reference available
- Guideline 4.k (Services for which government funding or other insurance coverage) - Removed; no CMS reference available
- Guideline 4.l (Services for which government funding or other insurance coverage)
  - Removed; no CMS reference available
- Guideline 4.m (Transportation of any potential donor for typing and matching) - Removed; no CMS reference available
- Guideline 4.n (Transportation and other non-clinical expenses of a living donor) - Removed; no CMS reference available
- Guideline 4.o (Antibiotics, hypertensives, and other drugs that are not directly related to rejection) - Removed; no CMS reference available
- Definitions - Removed the following definitions:
  - Donor (No CMS reference available)
  - FDA Approved Drugs [defined in cross reference Coverage Summary for Medications/Drugs (Outpatient/Part B)] in Guideline 3
  - Histocompatibility Testing (defined in the referenced NCD in Guideline 4.c)
  - Immunosuppressive Drugs (moved to Guideline 3)
  - Therapeutic Regimen (moved to Guideline 3)
  - Thoracic Duct Drainage (defined in the referenced NCD in Guideline 4.b)

10/24/2013 Annual review, no updates.

10/31/2012 Annual review; updated Guidelines #12 to include a note when a Medicare Advantage member is sent outside of the member’s community for transplant, UnitedHealthcare will arrange or pay for appropriate lodging and transportation for the member and a companion.
10/13/2011  Annual review; no updates.

10/21/2010  Updated link of the NCD for Stem Cell Transplantation (110.8.1) (Guidelines #6); NCD was updated based on CMS Decision Memo for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome.

09/07/2010  Policy updated to include guidelines for Umbilical Cord Blood Harvesting and Storage for Future Use.