Medicare C/D Medical Coverage Policy

Transplants: Solid Organ, Bone Marrow and Stem Cell Transplants

Origination: May 21, 2001
Review Date: January 29, 2015
Next review: January, 2017

DESCRIPTION OF PROCEDURE OR SERVICE
Solid organ and bone marrow transplants are necessary to replace end stage disease with donor’s healthy organ or cells. The purpose of transplant is to extend and improve the quality of life.

Stem Cells are used to repopulate the bone marrow of patients receiving high-dose chemotherapy/radiation therapy for a variety of neoplasms. Stem cells are also used to treat certain genetic diseases and anemias. The process involves harvesting stem cells from one of four sources: Bone marrow, Peripheral blood, embryonic/fetal or Umbilical cord/placenta.

Autologous transplant is defined as cells that are harvested from and returned to the same patient.

Allogenic transplant is defined as cells that are harvested from a healthy compatible donor and infused into a patient.

The harvesting or banking of autologous bone marrow or stem cells for future use, when myeloablative high-dose chemotherapy may be a necessary treatment option, is eligible for coverage when the following criteria are met.

POLICY STATEMENT
Coverage will be provided for transplants when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION
Please refer to the member’s individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions for members will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations;
• Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member’s particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE
1. Preauthorization by the Plan for the transplant procedure is required;

   AND

2. All Solid Organ, Bone Marrow and Stem Cell transplants must be recommended by a physician;

   AND

3. Documentation of the following:
   a. Documentation of organ failure, AND
   b. Documentation of transplantation candidacy as per facility guidelines/protocol ; AND
   c. The facility is approved by CMS as meeting institutional coverage criteria for performing transplants and is listed on the CMS certified facility list for the transplants;

4. If there is a NCD or LCD available for the specific transplant requested, the documentation should support the Medicare guidance indicated in the NCD or LCD.)

5. For bone marrow and stem cell transplants, CMS does not currently list certified facilities and therefore, the criteria as presented in the NCD must be met.

6. The following are CMS approved transplants:
   • Heart,
   • Artificial Heart (in a CMS qualified clinical trial),
   • Ventricular Assist Devices (VAD),
   • Heart/Lung,
   • Cornea,
   • Kidney,
   • Intestine,
   • Bone Marrow,
   • Liver,
   • Lung, and
   • Kidney/Pancreas. (A pancreas transplant can be performed with the kidney transplant or after the kidney transplant. If the Pancreas is transplanted
alone, it must be in a Medicare approved kidney transplant facility and meet criteria in the National Coverage Determination (NCD).

WHEN COVERAGE WILL NOT BE APPROVED
1. Transplants experimental/investigational in nature, unless in a qualified Medicare approved clinical trial.
2. Combined kidney & liver transplant;
3. Pancreas transplant for diabetic patients who have not experienced end stage renal failure secondary to diabetes.
4. Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial);
5. Facility is not approved by CMS as meeting institutional coverage criteria for transplants.
6. Adult liver transplantation for malignancies (excluding hepatocellular carcinoma);
7. Nationally non-covered indications in the respective NCD.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION
This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

*Applicable Codes: 32850, 32851, 32852, 32853, 32854, 32855, 32856, 33930, 33933 33935, 33940, 33944, 33945, 38204, 38205, 38206, 38207, 38208, 38209, 38210, 38211, 38212, 38213, 38214, 38215, 38230,38232, 38240, 38241, 38242, 44132, 44133, 44135, 44136, 44715, 44720, 44721, 47133, 47135, 47136, 47140, 47141, 47142, 47143, 47144, 47145, 47146, 47147, 48160, 48550, 48551, 48552, 488554, 50300, 50320, 50323, 50325, 50327, 50328, 50329, 50340, 50360, 50365, 50380,

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Eligible Services for an approved Organ or Stem Cell Transplant not participating in a clinical trial include:

1. Preoperative Care, including prophylactic dental care, i.e., including periodontal care;
2. Transplant Care, facility and professional fees;
3. Bone marrow (and peripheral stem cells) harvesting or donor fees, or Organ Procurement Fees, including organ donor fees;
4. Post-transplant care is covered as medical benefit, including immunosuppressant drugs;
5. A psychological evaluation by a trained psychologist is covered as a medical benefit as part of a transplant evaluation process;
6. Living donor expenses are eligible for coverage through the procurement process.

**SPECIAL NOTES**

1. **Immunosuppressive drugs** are covered as a medical benefit (Part B) for members after a Medicare covered transplant procedure.

2. The transplant facility must be approved by CMS as meeting institutional coverage criteria. These criteria usually require, in part, that the facilities meet the minimum standards to ensure the safety of beneficiaries receiving these services in order to be considered as a provider with the ability and expertise to perform the procedure. The Plan reserves the right to approve the facility where the Organ or Stem Cell transplant will be performed.

3. **Transportation and Lodging Expenses**: When the Plan pre-authorizes a member to receive transplant services at a facility located outside of the Plan’s service area, the Plan will cover reasonable expenses for transportation to and lodging at the distant location for the member and a companion. When transplant services are provided by a facility located inside the Plan’s service area, transportation and lodging expenses are not covered by the Plan.

**NOTES:**

- **Lodging** must be approved in advance and arranged through the transplant coordinator at the transplant center or the Plan.
- **Automobile expenses** will be reimbursed at the IRS-medical mile approved rate in effect on the date of travel.
- **Travel expenses** for the member are a covered expense. The amount reimbursed to the family member may be considered compensation and, therefore, be taxable. A tax specialist should be consulted by the recipient.
- **Reimbursement** of lodging will be based on the available lodging in the geographical area.

References:

3. Medicare National Coverage Determination (NCD) for Adult Liver Transplantation (ID#260.1); Effective date: 6/19/2006; Accessed via Internet at [www.cms.gov](http://www.cms.gov); viewed on 04/01/2014;
Policy Implementation/Update Information:

Revision Dates:
December 31, 2001 and February 22, 2002; June 22, 2005; February 21, 2007: No criteria changes made
June 17, 2009: New online policy format; removed Medical Director review required for all requests; clarified transportation and lodging section to remain compliant with new CMS regulations.
October 26, 2011: Added CMS language regarding distant location provision found in MCM Chp 4.
July 16, 2014: Annual review; applied updates according to NCDs; defined “normal community standard” to assist staff; added edits for further clarify per Medicare guidance. October 29, 2015 updated LCD due to ICD-10 update only.

Approval Dates:
Medical Coverage Policy Committee: January 29, 2015

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