



Medicare Part C Medical Coverage Policy

Transplant: Solid Organ

Origination: May 21, 2001
Review Date: November 4, 2022
Next review: November, 2024

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE OR SERVICE

Solid organ transplants are necessary to replace end stage disease with a donor's healthy organ. The purpose of a transplant is to extend and improve the member's quality of life.

POLICY STATEMENT

Coverage will be provided for transplants when it is determined to be medically necessary and the medical criteria/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 Determinations (NCD);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations;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 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 confirmed by facility verification to be a CMS certified facility for the transplant(s);

4. If there is a NCD available for the specific transplant being requested, the clinical documentation should support the Medicare guidance indicated in the NCD. Refer to NCD Transplantation: Solid Organ Transplants. <https://www.cms.gov/medicare-coverage-database/indexes/ncd-by-chapter-and-section-index.aspx?bc=AqAAAAAAAAAA&>

5. The following are CMS approved transplants:

- Heart,
- Artificial Heart (in a CMS qualified clinical trial),
- Ventricular Assist Devices (VAD),
- Cornea,
- Kidney,
- Intestine
- Liver,
- Lung,
- Kidney, and

- Pancreas.

*****Note***** When more than one solid organ transplant is requested to be performed at the same time, then Medical Director Review is required for approval.

WHEN COVERAGE WILL NOT BE APPROVED

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

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, 44132, 44133, 44135, 44136, 44715, 44720, 44721, 47133, 47135, , 47140, 47141, 47142, 47143, 47144, 47145, 47146, 47147, 48160, 48550, 48551, 48552, 48554, 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.

For an approved organ transplant, services eligible for coverage include:

1. Preoperative Care, including prophylactic dental care, i.e., including periodontal care;
2. Transplant Care, facility and professional fees;

3. 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. See Medical Coverage Policy “Immunosuppressant Medications.”
2. **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 (i.e. North Carolina), 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. Lodging must be approved in advance and arranged through the transplant coordinator at the transplant center or the Plan. (See Authorization Entry Guidelines)
3. Concerning Intestine Transplant Procedures: The program must be located in a hospital with a Medicare-approved liver program. This program includes multivisceral and combined liver-intestine transplants.
4. Concerning Pancreas Transplant Procedures: 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 Medicare approved kidney transplant facility and meet criteria in the National Coverage Determination (NCD).

References:

1. Medicare National Coverage Determination for Heart Transplants (ID #260.9); Effective date: 5/1/2008; accessed via Internet site <http://www.cms.gov> on 11/4/2022.
2. Medicare National Coverage Determination (NCD) for Pancreas Transplants (ID#260.3); Effective date: 4/26/2006; accessed via Internet site <http://www.cms.gov> on 11/4/2022.
3. Medicare National Coverage Determination (NCD) for Adult Liver Transplantation (ID#260.1); Effective date: 6/21/2012; Accessed via Internet at www.cms.gov; viewed on 11/4/2022;
4. Medicare National Coverage Determination (NCD) for Intestinal and Multi-Visceral Transplantation (ID#260.5); Effective date: 5/11/2006; accessed via Internet site <http://www.cms.gov> on 11/4/2022.
5. Medicare Decision Memo for Transplant Centers: Re-Evaluation of Criteria for Medicare Approval (CAG-00061N); Effective date: 7/26/00; accessed via Internet site <http://www.cms.gov> on 11/4/2022.
6. Medicare Managed Care Manual- Chapter 4- Benefits and Beneficiary Protections; Reviewed on 10/20/16; Section 30.4; Transportation Benefits (old reference) and section 10.11 Transplant Services. Accessed via internet site <http://www.cms.gov/manuals/downloads/mc86c04.pdf> on 11/4/2022;
7. Transplant Certification and Compliance; accessed via Internet site www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp#TopOfPage on 10/14/2020. (Old reference)
8. Medicare Local Coverage Determination for Immunosuppressive Drugs (L33824) – CGS Administrators; Effective date 07/01/2016; accessed via <http://www.cms.gov> 11/4/2022.
9. Medicare Approved Transplant programs viewed online at: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Transplant.html>; viewed on 11/4/2022.
10. Transplant Living.org viewed online at <https://transplantliving.org/financing-a-transplant/covering-costs/>; viewed on 11/4/2022.

11. Medicare Provider Reimbursement Manual; Part 1, Chapter 27, Reimbursement for ESRD and Transplant Services; DHHS; January 14, 2005; viewed online at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R30PR1.pdf> ; Viewed on 12/6/18. Accessed via internet on 11/4/2022
12. Medicare Local Coverage Determination (LCD) for Psychological and Neuropsychological Testing (L34646): Effective Date: 02/01/2016: Accessed via internet site www.cms.gov on 11/4/2022.

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.

December 21, 2016: Updated policy by separation of Solid Organ Transplant and Stem Cell information per CEC request for staff clarification.

February 20, 2019: Annual review and Staff Clarification: Indications for Coverage #3. c. The facility is approved by CMS as meeting institutional coverage criteria for performing transplants and is confirmed by facility provided documentation to be a CMS certified facility for the transplants; Indications for Coverage #4. Added Hyperlink to NCD for Solid Organs. Under Indications for Coverage #5. Added ***Note***When more than one solid organ transplant is requested to be performed at the same time (with the exception of Heart/Lung and Kidney/Pancreas combination transplants-which are CMS approved) then Medical Director Review is required for approval.

March 20, 2019: CMS Update: Indications for Coverage #5. Removed "(with the exception of Heart/Lung and Kidney/Pancreas combination transplants-which are CMS approved)" as CMS no longer has approved combination therapy procedures.

June 19, 2019: Updated Special Notes section with notes from the Intestine and Pancreas bullets under indications for coverage.

October 21, 2020: Staff Clarification; When Coverage Will Not be Approved: removed #2 "Combined kidney and liver transplant."

November 18, 2020: Staff Clarification; Indications for Coverage: 3. C. Removed "provided documentation" and added "verification".

November 4, 2022: Annual Review; No CMS updates; Minor Revisions only

Approval Dates:

Medical Coverage Policy Committee: November 16, 2022

Policy Owner: Beth Sell, RN, BSN
Medical Policy Coordinator