Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Heart Transplants	MP-HT-FP-01-23	☒ MMM MA ☐ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Other: Transplants
Heart Transplants

The following clinical policy addresses Heart Transplantation.

A heart transplant is an operation in which a failing heart is replaced with a healthier donor heart. Heart transplant is a treatment that's usually reserved for people whose condition hasn't improved enough with medications or surgeries.

Heart transplants involve the removal of either all or part of a cadaver heart and its implantation into a recipient. There are two types of cardiac transplant: orthotopic and heterotopic. Orthotopic transplant is the more common of the two methods and involves replacing the recipient heart with the donor heart implanting the ventricles of the donor heart onto the right atria and main arteries of the recipient's heart. Heterotopic transplants involve placing the entire donor heart into the chest cavity and surgically attaching it to the recipient's entire heart.

The limiting factor for heart transplantation is the short supply of donor organs. The procurement and distribution of heart organs for transplantation in the U.S. is under the direction of United Network for Organ Sharing (UNOS). A policy for allocation of heart and heart-lung organs prioritizes donor heart organs according to the principles of medical urgency (UNOS, 2023).

Please note that all services described in this policy require prior authorization.

- Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.
- Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.
- Providers must submit all required and requested documentation for case evaluation and determination.
- The plan may request additional documentation and information not received and or provided initially related to condition and diagnosis for case evaluation and determination.
- Any additional documentation submitted specifying medical necessity criteria and considered important for case evaluation and determination will be reviewed by Clinical Team utilizing guidelines and regulation criteria.

Service Description

NCD 260.9
Indications and Limitations of Coverage
A. General

Cardiac transplantation is covered under Medicare when performed in a facility which is approved by Medicare as meeting institutional coverage criteria. (See CMS Ruling 87-1.)

CMS Ruling No. 87-1
Date: April, 1987

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling provides criteria that facilities must comply with in order to obtain approval for payment for heart transplants. It rescinds HCFAR 80-1, which excluded heart transplants from coverage under Medicare. Coverage as a result of this Ruling may be effective as early as October 17, 1986 under some circumstances, as specified in the effective date section.

MEDICARE PROGRAM
Hospital Insurance Benefits (Part A)
Criteria for Medicare Coverage of Heart Transplants

HCFAR 87-1 Purpose: This Ruling rescinds HCFA Ruling HCFAR 80-1 that excluded coverage of heart transplants under the Medicare program. It also provides public notice of HCFA's new coverage policy for heart transplants.

Citations: Sections 1102, 1862(a)(1) and 1871 of the Social Security Act (42 U.S.C. 1302, 1395y(a)(1) and 1395hh), 52 FR 10935.1

Ruling: HCFAR 80-1 that excludes heart transplants from coverage under the Medicare program is rescinded. Facilities that wish to obtain coverage of heart 1 Editor's note: This Ruling appeared in the Federal Register of April 6, 1987 (52 FR 10935) as part of a Notice of Ruling. Additional background information and pertinent history are available in that document. The Ruling is printed without change except for correction of obvious typographical errors. We especially note correct wording of criteria 5.d. and 5.e. under section A, "Criteria for Facilities." transplants for their Medicare patients must submit an application and supply documentation showing their initial and ongoing compliance with each of the criteria. For facilities which are approved, Medicare will cover under Part A (Hospital Insurance) all medically reasonable and necessary inpatient services. Payment for these services generally will be made under the Diagnosis Related Group (DRG)

classification code #103, "Heart transplants". Organ acquisition costs will be paid separately on a cost-reimbursement basis. Physician services, related to the transplant,

HCFAR 87-1-2 as well as non-hospital services related to pre-and post-transplant care, will be covered under Part B (Supplementary Medical Insurance) and reimbursed on the basis of reasonable charges. In accordance with the provisions of section 9335(c) of OBRA, post-transplant care for covered transplants includes outpatient, self-administrable immunosuppressant drugs, such as cyclosporine, for a period of up to one year beginning with the date of discharge from the inpatient hospital stay during which the transplant was performed. If a Medicare beneficiary receives a covered heart transplant from an approved facility, reasonable and necessary services for followup care and for complications are covered, even if such services are furnished by a hospital that is eligible for Medicare reimbursement but is not specifically approved by Medicare for heart transplantation.

Medicare will not cover transplants or re-transplants in facilities which have not been approved as Medicare transplant facilities. If a Medicare beneficiary receives a heart transplant from a facility that is not approved by Medicare for heart transplantation, we will not cover any inpatient services associated with the transplantation procedure. Neither will we cover physician services associated with the transplantation procedure. Thus, payment will not be made for the performance of the transplant or for any other services which are incorporated into a global fee. However, after a beneficiary has been discharged from a hospital (which has not been approved by Medicare as a heart transplant center) in which he or she receives the heart transplant, medical and hospital services required as a result of the prior non-covered transplant may be covered in

HCFAR 87-1-3 a facility otherwise eligible for Medicare reimbursement when they are reasonable and necessary in all other respects. Thus, coverage will be provided for subsequent inpatient stays or outpatient treatment (exclusive of self-administrable immunosuppressive drugs) ordinarily covered by Medicare even if the need for treatment arose because of a previous non-covered heart transplant procedure. These services also will be covered for Medicare beneficiaries who were not beneficiaries at the time they received a heart transplant regardless of whether or not the transplant was performed at an approved facility.

NCD 260.9
Indications and Limitations of Coverage
B. Exceptions

In certain limited cases, exceptions to the criteria may be warranted if there is justification and if the facility ensures our objectives of safety and efficacy. Under no circumstances will exceptions be made for facilities whose transplant programs have been in existence for less than 2 years, and applications from consortia will not be approved.

Although consortium arrangements will not be approved for payment of Medicare heart transplants, consideration will be given to applications from heart transplant facilities that consist of more than one hospital where all of the following conditions exist:

-The hospitals are under the common control or have a formal affiliation arrangement with each other under the auspices of an organization such as a university or a legally constituted medical research institute; and

-The hospitals share resources by routinely using the same personnel or services in their transplant programs.
-The sharing of resources must be supported by the submission of operative notes or other information that documents the routine use of the same personnel and services in all of the individual hospitals. At a minimum, shared resources means:
-The individual members of the transplant team, consisting of the cardiac transplant surgeons, cardiologists and pathologists, must practice in all the hospitals and it can be documented that they otherwise function as members of the transplant team; and
-The same organ procurement organization, immunology, and tissue-typing services must be used by all the hospitals;
-The hospitals submit, in the manner required (Kaplan-Meier method) their individual and pooled experience and survival data; and
-The hospitals otherwise meet the remaining Medicare criteria for heart transplant facilities; that is, the criteria regarding patient selection, patient management, program commitment, etc.

C. Pediatric Hospitals

Cardiac transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric heart transplants if the hospital submits an application which CMS approves as documenting that:

-The hospital's pediatric heart transplant program is operated jointly by the hospital and another facility that has been found by CMS to meet the institutional coverage criteria in CMS Ruling 87-1;
-The unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and
-The hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

D. Follow-Up Care

Follow-up care required as a result of a covered heart transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hospital after receiving a noncovered heart transplant. Coverage for follow-up care would be for items and services that are reasonable and necessary, as determined by Medicare guidelines. (See the Medicare Benefit Policy Manual , Chapter 16, "General Exclusions From Coverage," §180.)

E. Immunosuppressive Drugs

See the Medicare Claims Processing Manuals , Chapter 17, "Drugs and Biologicals," §§80.3.1 and, Chapter 8, "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," §120.1.

F. Artificial Hearts

Medicare covers ventricular assist devices (VAD) and artificial hearts when implanted under the coverage criteria stated in §20.9 of this manual (NCD Manual 100-03).

(This NCD last reviewed April 2008.)

Medical Necessity Guidelines

D. Guidelines for Patient Selection Criteria Included in section A., Criteria for Facilities, is the requirement that a facility must have adequate written patient selection criteria and an implementation plan for their application.

HCFAR 87-1-16 Such criteria should include or be comparable to, but need not be limited to, the guidelines below that indicate the type of factors or areas we would like to see addressed. We expect to disapprove any facility that departs so significantly from the guidelines that Medicare beneficiaries would be placed at risk.

1. Patient selection criteria must be based upon both a critical medical need for transplantation and a maximum likelihood of successful clinical outcome.
2. The patient must have a very poor prognosis (for example, less than a 25 percent likelihood of survival for six months) as a result of poor cardiac status but must otherwise have a good prognosis.
3. All other medical and surgical therapies that might be expected to yield both short- and long-term survival (for example, 3 or 5 years), comparable to that of cardiac transplantation, must have been tried or considered.
4. Many factors must be recognized at the present time to exert an adverse influence on the outcome after cardiac transplantation. The manner and extent to which adverse risk is translated into contraindication varies. A patient who meets patient selection criteria under section D. 2., 3., and 5., and is free of the adverse factors under this section 4a. and b., is considered a good candidate for cardiac transplantation. Some experts would not require freedom from all adverse

HCFAR 87-1-17 factors under this section 4b. We recognize that some who may not be considered "good candidates" may also benefit, but the likelihood or extent of benefit is significantly less.

a. Strongly adverse factors include:

(1) Advancing age; for example, a patient beyond 53 to 57 years of age (the mid-50's). Until not long ago, limited experience with patients over age 50 showed that these patients had both impaired capacity to withstand post-operative and immunosuppressive complications and lessened survival. More recently, carefully selected patients through age 55 have had good survival experience; but experience with patients beyond age 55 is limited. The selection of any patient for transplantation beyond age 50 must be done with particular care to ensure an adequately young "physiologic" age and the absence or insignificance of coexisting disease.

(2) Severe pulmonary hypertension (because of the limited work capacity of the typical donor right ventricle which is an important consideration in orthotopic cardiac transplantation). Generally, pulmonary vascular resistance above 5 Wood units or pulmonary artery systolic pressure over 65 mm Hg is

HCFAR 87-1-18 a serious adverse factor. However, these patients may be acceptable if a pulmonary vasodilator drug reduces both pulmonary vascular resistance below 3 Wood units and pulmonary artery systolic pressure below 50 mm Hg.

(3) Renal or hepatic dysfunction not explained by the underlying heart failure and not deemed reversible (because of the nephrotoxicity and hepatotoxicity of cyclosporine). For patients who are to receive azathioprine and high-dose corticosteroid rather than cyclosporine, a slightly higher level of hepatic or renal dysfunction is acceptable, but substantial dysfunction is still a contraindication (because of the likelihood of early exacerbation postoperatively and because of interference with immunosuppressive regimens).

(4) Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital end-organs (because of a substantially less favorable prognosis for survival than for the average transplant recipient).

(5) Symptomatic peripheral or cerebrovascular disease (because of accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment).

HCFAR 87-1-19

(6) Chronic obstructive pulmonary disease or chronic bronchitis (because of poor postoperative course and likelihood of exacerbation of infection with immunosuppression).

(7) Active systemic infection (because of the likelihood of exacerbation with initiation of immunosuppression).

(8) Recent and unresolved pulmonary infarction, pulmonary roentgenographic evidence of infection, or of abnormalities of unclear etiology (because of the likelihood that this represents pulmonary infection).

(9) Systemic hypertension, either at transplantation or prior to development of end-stage heart disease, that required multi-drug therapy for even moderate control (for example, multidrugs to bring diastolic pressure below 105 mm Hg) for patients who would be on cyclosporine protocols (because of the substantial exacerbation of hypertension with cyclosporine and the difficulty of its management).

(10) Any other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation.

HCFAR 87-1-20

(11) Cachexia, even in the absence of major end organ failure (because of the significantly less favorable survival of these patients).

(12) The need for or prior transplantation of a second organ such as lung, liver, kidney, or marrow (because this represents the coexistence of significant disease, and because multi-organ transplantation must still be considered experimental).

(13) A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regimen (because a lifelong medical regimen is necessary, requiring multiple drugs several times a day, with serious consequences in the event of their interruption or excessive consumption).

(14) The use of a donor heart, that may have had its effectiveness compromised by such factors as the use of substantial vasopressors prior to its removal from the donor, its prolonged or compromised maintenance between the time of its removal from the donor and its implantation into the patient, or pre-existing disease.

HCFAR 87-1-21

b. Other factors given less adverse weight by some experts but considered importantly adverse by others include:

(1) Insulin-requiring diabetes mellitus, in the judgment of most experts (because the diabetes is often accompanied by occult vascular disease and because the diabetes and its complications are exacerbated by chronic corticosteroid therapy; even current cyclosporine immunosuppression regimens require chronic long-term corticosteroid, though at a lower dose, and high dose corticosteroid is used in the treatment of acute rejection).

(2) Asymptomatic severe peripheral or cerebrovascular disease (because of accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment).

(3) Documented peptic ulcer disease (because of the likelihood of early postoperative exacerbation).

(4) Current or recent history of diverticulitis (which must be considered a source of active infection that may be exacerbated with the initiation of immunosuppressant).
5. Plans for long-term adherence to a disciplined medical regimen must be feasible and realistic for the individual patient.

HCFAR 87-1-22 Effective Dates: October 17, 1986 for those facilities which would have qualified as heart transplant facilities when the transplant was performed and whose applications are received by HCFA by July 6, 1987. The effective date of coverage for heart transplants performed at facilities applying after July 6, 1987 is the date the facility receives approval as a heart transplant facility from HCFA.

Heart Transplant is medically necessary when the member meets the transplanting institution´s protocol eligibility criteria.

1. Heart transplantation medically necessary for heart failure with irreversible underlying etiology, including the following indications when the selection criteria listed below are met and none of the absolute contraindications is present:
   - Cardiac arrhythmia
   - Cardiogenic shock
   - Severe Heart Failure
     - ✓ New York Heart Association class III or IV despite maximally tolerated guideline directed medical therapy (GDMT)
     - ✓ Peak metabolic oxygen consumption on cardiopulmonary exercise test less than 14 mL/kg/min or less than 12 mL/kg/min if patient on beta-blocker
     - ✓ Peak metabolic oxygen consumption on cardiopulmonary exercise test less than 50% predicted based on patient age, sex, and weight
   - Cardiac re-transplantation due to graft failure
   - Cardiomyopathy due to nutritional, metabolic, hypertrophic or restrictive etiologies
   - Congenital heart disease
   - End-stage ventricular failure
   - Idiopathic dilated cardiomyopathy
   - Inability to be weaned from temporary cardiac-assist devices after myocardial infarction or non-transplant cardiac surgery
   - Intractable coronary artery disease
   - Myocarditis
   - Post-partum cardiomyopathy
   - Right ventricular dysplasia/cardiomyopathy
   - Valvular heart disease

Heart Diagnosis Categories

Heart diagnosis categories	Heart diagnosis
Cardiomyopathy	Dilated Myopathy: Idiopathic
	Dilated Myopathy: Myocarditis
	Dilated Myopathy: Other Specify
	Dilated Myopathy: Post Partum

	Dilated Myopathy: Familial Dilated Myopathy: Adriamycin Dilated Myopathy: Viral Dilated Myopathy: Alcoholic Hypertrophic Cardiomyopathy Restrictive Myopathy: Idiopathic Restrictive Myopathy: Amyloidosis Restrictive Myopathy: Sarcoidosis Restrictive Myopathy: Endocardial Fibrosis Restrictive Myopathy: Other Specify Restrictive Myopathy: Secondary to Radiation/Chemotherapy
Coronary Artery Disease	Coronary Artery Disease Dilated Myopathy: Ischemic
Congenital Heart Disease	Congenital Heart Disease
Valvular Heart Disease	Valvular Heart Disease
Retransplant/Graft Failure	Heart Retransplant/Graft Failure: Coronary Artery Disease Heart Retransplant/Graft Failure: Other Specify Heart Retransplant/Graft Failure: Non-Specific Heart Retransplant/Graft Failure: Acute Rejection Heart Retransplant/Graft Failure: Hyperacute Rejection Heart Retransplant/Graft Failure: Primary Failure Heart Retransplant/Graft Failure: Chronic Rejection Heart Retransplant/Graft Failure: Restrictive/Constrictive
Other	Cardiac Disease: Other Specify Heart: Other Specify Cancer

The most commonly used classification system, the New York Heart Association (NYHA) Functional Classification[1], places patients in one of four categories based on limitations of physical activity.

Class Patient Symptoms

The table below describes the different classes in the NYHA Functional Classification.	
Class	**Patient Symptoms**
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or shortness of breath.
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, shortness of breath or chest pain.
III	**Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, shortness of breath or chest pain.**
IV	**Symptoms of heart failure at rest. Any physical activity causes further discomfort.**

2. Absolute contraindications **for Transplant *Recipients*** include, but are not limited to, the following:

A. Metastatic Cancer

B. Systemic illness that will limit survival despite heart transplant.

1. Neoplasm other than skin. Low-grade prostate that has not been "cured" (by prostate-specific antigen measurement) or in remission less than 5 years is generally recognized as a contraindication.
2. HIV/AIDS (CDC definition of CD4 count of <200 cells/mm^3).
3. Systemic lupus erythematosus or sarcoid that has multisystem involvement and is still active.
4. Any systemic process with a high probability of recurring in the transplanted heart.

C. Fixed pulmonary hypertension (both 1 and 2 are arbitrary values).

1. Pulmonary vascular resistance >5 Wood units.

2. Trans-pulmonary gradient >15 mm/Hg.

D. Age over 70 years.

E. Demonstrated patient noncompliance, which places the organ at risk by not adhering to medical recommendations.

Limits or Restrictions

Cardiac transplantation is covered under Medicare when performed in a facility which is approved by Medicare as meeting institutional coverage criteria. Medicare will not cover transplants or re-transplants in facilities which have not been approved as Medicare transplant facilities.

Reference Information

American Heart Association Classes and Stages of Heart Failure
Link: https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure

Centers for Medicare and Medicaid Services. National Coverage Determination for Heart Transplants. NCD #260.9. Effective May 1, 2008
Link: https://www.cms.gov/medicare-coverage-database/search.aspx

CMS
NCD 260.9
Heart Transplants
Medicare Coverage Database (MCD)
Link: https://www.cms.gov/medicare-coverage-database/search.aspx

CMS Ruling 87-1
Link: https://www.cms.gov/medicare/appeals-and-grievances/orgmedffsappeals/downloads/hcfar871v508.pdf

MCG 27th Edition Heart Transplant

Organ Procurement & Transplantation Network (OPTN) Link: https://optn.transplant.hrsa.gov/

Steinman TL, Becker BN, Frost AE, et al. Clinical Practice Committee, American Society of Transplantation. Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplantation. 2001; 71(9):1189-1204.

United Network for Organ Sharing (UNOS). Policy 6 Organ Distribution: Allocation of Hearts and Heart-Lungs. Updated 12/13/2023. Link: http://optn.transplant.hrsa.gov/governance/policies/

Policy History

Date	Version	Comments
12/07/2023	Draft	New Medical Policy
12/15/2023	Final	Approved by Medical Policy Committee