

CHAMPVA POLICY MANUAL

CHAPTER: 2
SECTION: 31.2
TITLE: HEART TRANSPLANTATION

AUTHORITY: 38 CFR 17.270(a) and 17.272(a)

RELATED AUTHORITY: 32 CFR 199.4(e)(5)(vi)

I. EFFECTIVE DATE

A. On or after November 7, 1986, for services and supplies related to heart transplantation.

B. September 30, 1994, for the HeartMate® Implantable Pneumatic Left Ventricular Assist System (IPLVAS).

II. PROCEDURE CODE(S)

CPT Codes: 33940-33945, and 33975-33980

III. POLICY

A. Benefits are allowed for heart transplantation for beneficiaries who:

1. have an end-stage cardiac disease who have exhausted alternative medical and surgical treatments,
2. have a very poor prognosis as a result of poor cardiac functional status, and
3. have a long-term adherence to disciplined medical regimen are feasible and realistic.

B. The following services are covered for:

1. transplantation performed in an authorized Medicare-certified, TRICARE-certified, or TRICARE-certified pediatric heart transplantation center.
2. evaluation of potential candidate's suitability for heart transplantation, whether or not the patient is ultimately accepted as a candidate for transplantation;
3. pre- and post-transplant inpatient hospital and outpatient services;
4. pre- and post-operative services of the transplant team;

5. the donor acquisition team, the costs of transportation to the location of the donor organ, the transportation of the team, and the donated organ to the location of the transplantation center;
6. maintenance for the viability of the donor organ following a formal declaration of brain death and after all existing legal requirements for excision of the donor organ have been met;
7. blood and blood products;
8. FDA approved immunosuppression drugs and off-label use drugs when determined to be medically necessary and generally accepted practice within the general medical community (i.e., proven);
9. services and supplies, including inpatient care, **that are needed to treat complications of the transplant procedure, including management of infection and rejection episodes;**
10. services and supplies which are medically necessary for the periodic evaluation and assessment of the successfully transplanted patient;
11. cardiac rehabilitation (see [Chapter 2, Section 4.9, Cardiac Rehabilitation](#));
12. DNA-HLA tissue typing in determining histocompatibility;
13. **donor costs;**
14. **transportation of the patient by air ambulance may be cost shared when determined to be medically necessary (see [Chapter 2, Section 32.1, Ambulance Service](#)); and**
15. for Hepatitis B and pneumococcal vaccines for patients undergoing transplantation.

IV. POLICY CONSIDERATIONS

A. **Pre-authorization or retrospective authorization of heart transplantation is required. When pre-authorization was not obtained, but patient meets (or as of the date of transplantation, would have met) the patient selection criteria, CHAMPVA benefits may be extended.**

B. Transplant facility is (or at time of transplantation, would have been) a Medicare-certified, TRICARE-certified, or **TRICARE-certified pediatric heart transplantation center** at the time of transplant.

C. Claims for services and supplies related to the transplant will be reimbursed based on billed charges.

D. Claims for transportation of the donor organ and transplant team shall be paid as billed, but not to exceed the transport service's published schedule of charges, and cost shared on an inpatient basis. Scheduled or chartered transportation may be cost shared.

E. Benefits will be allowed for donor costs (see [Chapter 2, Section 31.1](#), *Donor Costs*).

F. Charges made by the donor hospital will be cost shared on an inpatient basis and must be fully itemized and billed by the transplant center in the name of the CHAMPVA patient.

G. Acquisition and donor costs are not considered to be components of the services covered under the DRG. These costs must be billed separately on a CHAMPVA claim form in the name of the CHAMPVA patient.

H. When patient is discharged from the hospital (less than 24 hours) due to circumstances that prohibit the authorized transplant, such as the available organ is found not suitable, all charges will be cost shared on an inpatient basis. When admitted, the expected stay was for more than 24 hrs.

I. Heart transplantation to include use of the HeartMate® IPLVAS must be deemed medically necessary by a cardiologist or cardiothoracic surgeon. Heart transplantation is contraindicating when any if the following conditions exit:

1. advancing age (because of diminished capacity to withstand postoperative complications);
2. severe pulmonary hypertension (because of the limited work capacity of the typical donor right ventricle). A pulmonary vascular resistance above 5 wood units or pulmonary artery systolic pressure over 65 mm Hg is considered to be severe pulmonary hypertension;
3. renal or hepatic dysfunction not explained by the underlying heart failure and not deemed reversible (because of the nephrotoxicity and hepatotoxicity of cyclosporin);
4. acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of a vital end-organ (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 chronic corticosteroid treatment);

6. chronic obstructive pulmonary disease or chronic bronchitis (because 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 or 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 cardiac disease, that requires multi-drug therapy for even moderate control (multi-drugs to bring diastolic pressure below 105 mm Hg);
10. other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation;
11. cachexia, even in the absence of major end-organ failure (because of the significantly less favorable survival of such patients);
12. the need for or prior transplantation of a second organ such as lung, liver, kidney, or marrow (because this represents the co-existence of significant disease) (see [Chapter 2, Section 31.3, Heart-Lung Transplantation](#));
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, the long-term effectiveness of which might be compromised by such actions 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;
15. insulin-requiring diabetes mellitus (because the diabetes is often accompanied by occult vascular disease and because the diabetes and its complications are exacerbated by chronic corticosteroid therapy);
16. asymptomatic severe peripheral or cerebrovascular disease (because of accelerated progression in some patients after cardiac transplantation and chronic corticosteroid treatment);
17. peptic ulcer disease (because of the likelihood of early postoperative exacerbation); or

18. current or recent history of diverticulitis (considered as a source of active infection which may be exacerbated with the initiation of immunosuppressant therapy).

V. EXCEPTIONS

A. Heart transplantation and all services and supplies for inpatient and outpatient care performed in **an unauthorized Medicare-certified or TRICARE-certified approved transplantation center, or a TRICARE-certified pediatric heart transplantation center,** may be cost shared subject to applicable CHAMPVA Program policy. This exception is also applicable to heart **transplantations** performed prior to November 7, 1986.

B. Heart transplantations performed on an emergency basis in **an unauthorized** heart transplant facility may be cost shared only when the following conditions have been met.

1. The unauthorized center must consult with the nearest Medicare-certified, TRICARE-certified, or **TRICARE-certified pediatric heart transplantation center,** regarding the transplantation case.

2. It must be determined and documented by the transplant team physician(s) at approved center that transfer of the patient (to the approved center) is not medically reasonable, even though transplantation is feasible and appropriate.

C. The HeartMate® IPLVAS is intended for temporary mechanical circulatory support for transplant candidates in non-reversible left ventricular failure as a bridge to cardiac transplantation. The intent of the HeartMate® IPLVAS therapy is to provide hemodynamic support while awaiting transplantation. This device is intended for long-term support until a donor heart is available. Bridge to cardiac transplantation utilizing the HeartMate® IPLVAS may be cost shared by CHAMPVA only when the following conditions have been met:

1. there is written evidence that, at the time of implantation of the HeartMate® IPLVAS device, the patient had received unrestricted approval for cardiac transplantation from a Medicare approved transplantation facility;

Note: Approval by the transplantation facility in no way guarantees approval for cardiac transplantation by CHAMPVA.

2. on therapeutic doses of cardiac inotropic medications;
3. on an intra-aortic balloon pump (if possible); and
4. left atrial pressure or pulmonary capillary wedge is equal to or greater than 20mm Hg with either a systolic blood pressure equal to or less than 80mm Hg orb. Cardiac index of equal to or less than 2.01/min/m2.

VI. EXCLUSIONS

A. Services/supplies provided at no cost or if the beneficiary (or sponsor) has no legal obligation to pay. This includes expenses or charges that are waived by the transplantation center. [38 CFR 17.272(a)(1)]

B. Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program; unproven procedure). [38 CFR 17.272(a)(13)]

C. Services, supplies or devices, even those used in lieu of the transplant, when determined to be related or integral to an experimental or investigational (unproven) procedure may not be cost shared (see [Chapter 2, Section 16.5, Experimental/Investigational \(Unproven\) Procedures](#)). [38 CFR 17.272(a)(14)]

D. Pre- or post-transplant nonmedical expenses (i.e., out-of-hospital living expenses to include, hotel, meals, privately owned vehicle for the beneficiary or family members). [38 CFR 17.272(a)(4)]

E. The transportation of an organ donor or cadaver. [38 CFR 17.272(a)(59)].

F. Administration of an experimental or investigational (unproven) immunosuppressant drug that is not FDA approved or has not received CHAMPVA approval as an appropriate "off label" drug indication (see [Chapter 2, Section 30.8, Immunosuppression Therapy](#)).

G. Implantable devices intended for temporary mechanical circulatory support as a bridge to cardiac transplantation are considered experimental (unproven) and may not be cost shared under CHAMPVA. For exceptions to policy, see Paragraph C under EXCEPTIONS. Refer to [Chapter 2, Section 4.1, Cardiovascular System](#), regarding coverage of ventricular assist devices for use other than bridge to transplantation.

H. Prolonged extracorporeal circulation for cardiopulmonary insufficiency.

END OF POLICY*