Chapter 4 Section 24.2

Heart Transplantation

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1.0 CPT[1] PROCEDURE CODES

33940 - 33945, 33975 - 33980

2.0 POLICY

2.1 Benefits are allowed for heart transplantation.

2.1.1 A TRICARE Prime enrollee must have a referral from his/her Primary Care Manager (PCM) and an authorization from the contractor before obtaining transplant-related services. If network providers furnish transplant-related services without prior PCM referral and contractor authorization, penalties will be administered according to TRICARE network provider agreements. If Prime enrollees receive transplant-related services from non-network civilian providers without the required PCM referral and contractor authorization, Managed Care Support Contractors (MCSCs) shall reimburse charges for the services on a Point of Service (POS) basis. Special cost-sharing requirements apply to POS claims.

2.1.2 For Standard and Extra patients (through December 31, 2017) and TRICARE Select enrollees (starting January 1, 2018) residing in a Managed Care Support (MCS) region, preauthorization authority is the responsibility of the MCS Medical Director or other designated utilization staff.

2.2 Benefits are allowed for heart transplantation when the transplant is performed at a TRICARE or Medicare-certified heart transplant center or TRICARE-certified pediatric consortium heart transplantation center, for beneficiaries who:

2.2.1 Have an end-stage cardiac disease who have exhausted alternative medical and surgical treatments; and

2.2.2 Have a very poor prognosis as a result of poor cardiac functional status; and

2.2.3 For whom plans for long-term adherence to a disciplined medical regimen are feasible.

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2.3 In addition to meeting the above patient selection criteria, the following adverse factors must be absent or minimized:

2.3.1 Advancing age (because of diminished capacity to withstand postoperative complications). The selection of any patients 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.

2.3.2 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.

2.3.3 Renal or hepatic dysfunction not explained by the underlying heart failure and not deemed reversible (because of the nephrotoxicity and hepatotoxicity of cyclosporin).

2.3.4 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).

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

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

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

2.3.8 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).

2.3.9 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). Other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation.

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

2.3.11 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).

2.3.12 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).

2.3.13 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.

2.3.14 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).

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

2.3.16 Peptic ulcer disease (because of the likelihood of early postoperative exacerbation); and

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

2.4 Services and supplies related to heart transplantation are covered for:

2.4.1 Evaluation of a potential candidate's suitability for heart transplantation whether or not the patient is ultimately accepted as a candidate for transplantation.

2.4.2 Pre- and post-transplant inpatient hospital and outpatient services.

2.4.3 Pre- and post-operative services of the transplant team.

2.4.4 The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplantation center.

2.4.5 The maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met.

2.4.6 Blood and blood products.

2.4.7 U.S. Food and Drug Administration (FDA) approved immunosuppression drugs to include off-label uses when reliable evidence documents the off-label use is safe, effective, and provided in accordance with nationally accepted standards of practice in the medical community (proven).

2.4.8 Complications of the transplant procedure, including inpatient care, management of infection and rejection episodes.

2.4.9 Periodic evaluation and assessment of the successfully transplanted patient.

2.4.10 Cardiac rehabilitation.

2.4.11 Deoxyribonucleic Acid-Human Leucocyte Antigen (DNA-HLA) tissue typing in determining histocompatibility.

2.4.12 Donor costs.

2.4.13 Transportation of the patient by life support air ambulance and the services of a certified life support attendant.

2.5 Ventricular assist devices are covered if the device is FDA approved and used in accordance with FDA approved indications.

2.6 The SynCardia temporary Total Artificial Heart (TAH) for the treatment of end-stage biventricular heart failure is covered when used as a bridge to heart transplantation.

2.7 TAHs as destination therapy may be covered if the device has received a Humanitarian Device Exemption (HDE) from the FDA, and the device is used in accordance with FDA approved indications. See Chapter 8, Section 5.1 for the policy regarding HDEs.

2.8 AlloMap® molecular expression testing for cardiac transplant rejection surveillance.

3.0 POLICY CONSIDERATIONS

3.1 For beneficiaries who reside in TRICARE regions but fail to obtain preauthorization for heart transplantation, benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing authority is responsible for reviewing the claims to determine whether the beneficiary's condition meets the clinical criteria for the heart transplant. Charges for transplant and transplant-related services provided to TRICARE Prime enrollees who failed to obtain PCM referral and contractor authorization will be reimbursed only under POS rules.

3.2 Benefits will only be allowed for transplants performed at a TRICARE or Medicare approved heart transplantation center. Benefits are also allowed for transplants performed at a pediatric facility that is TRICARE-certified as a heart transplantation center on the basis that the center belongs to a pediatric consortium program whose combined experience and survival data meet the TRICARE criteria for certification. The contractor in whose jurisdiction the center is located is the certifying authority for TRICARE authorization as a heart transplantation center. Refer to Chapter 11, Section 7.1 for organ transplant center certification requirements.

3.3 Heart transplantation will be paid under the Diagnostic Related Group (DRG).

3.4 Claims for transportation of the donor organ and transplant team shall be adjudicated on the basis of billed charges, 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.

3.5 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 TRICARE patient.

3.6 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 standard Centers for Medicare and Medicaid Services (CMS) 1450 UB-04 claim form in the name of the TRICARE patient.

3.7 When a properly preauthorized transplant candidate is discharged less than 24 hours after admission because of extenuating circumstances, such as the available organ is found not suitable or other circumstances which prohibit the transplant from being timely performed, all otherwise authorized services associated with the admission shall be cost-shared on an inpatient basis, since the expectation at admission was that the patient would remain more than 24 hours.

3.8 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:

3.8.1 The unauthorized center must consult with the nearest TRICARE or Medicare-approved center regarding the transplantation case; and

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

4.0 EXCLUSIONS

4.1 Expenses waived by the transplant center (e.g., beneficiary/sponsor not financially liable).

4.2 Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program; unproven procedure).

4.3 Administration of an unproven immunosuppressant drug that is not FDA approved or has not received approval as an appropriate "off-label" drug indication.

4.4 Pre- or post-transplant nonmedical expenses (e.g., out-of-hospital living expenses, to include hotel, meals, privately owned vehicle for the beneficiary or family members).

4.5 Transportation of an organ donor.

4.6 Prolonged extracorporeal circulation for cardiopulmonary insufficiency (CPT[2] procedure codes 33960 and 33961).

5.0 EFFECTIVE DATES

5.1 November 7, 1986, for heart transplants.

5.2 The date of FDA approval for ventricular assist devices.

5.3 July 18, 2005, for the SynCardia temporary TAH as a bridge to heart transplantation.

5.4 The date of FDA approval for TAHs as destination therapy.

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5.5 February 19, 2015, for AlloMap® molecular expression testing for cardiac transplant rejection surveillance.

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