Preauthorization is required and must be obtained through Case Management.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

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Description

A heart transplant consists of replacing a diseased heart with a healthy donor heart. Transplantation is used for patients with refractory end-stage cardiac disease.

Summary of Evidence

The evidence for the use of heart transplant in patients who have end-stage heart failure includes case series and registry data. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. Despite an improvement in prognosis for many patients with advanced heart disease, heart transplant remains a viable treatment for those who have exhausted other medical or surgical remedies, yet are still in end-stage disease. Given the exceedingly poor survival without transplantation of patients who have exhausted other treatments, evidence of posttransplant survival is sufficient to demonstrate that heart transplantation provides a survival benefit in appropriately selected patients. Heart transplantation is contraindicated in patients in whom the procedure is expected to be futile due to comorbid disease or in whom posttransplantation care is expected to significantly worsen comorbid conditions. Similarly, evidence suggests that heart retransplantation after a failed primary heart transplant provides a survival benefit in patients who still meet criteria for heart transplantation and do not have contraindications.

Policy

Human heart transplantation may be considered medically necessary for selected adults and children with end-stage heart failure when patient selection criteria are met.
**Adult Patients**

I. Accepted Indications for Transplantation

1. Hemodynamic compromise due to heart failure demonstrated by any of the following three bulleted items,
   - Maximal VO\(_2\) (oxygen consumption) less than 10 mL/kg/min with achievement of anaerobic metabolism
   - Refractory cardiogenic shock
   - Documented dependence on intravenous inotropic support to maintain adequate organ perfusion,
   or
2. Severe ischemia consistently limiting routine activity not amenable to bypass surgery or angioplasty, or
3. Recurrent symptomatic ventricular arrhythmias refractory to ALL accepted therapeutic modalities.

II. Probable Indications for Cardiac Transplantation

1. Maximal VO\(_2\) less than 14 mL/kg/min and major limitation of the patient’s activities, or
2. Recurrent unstable ischemia not amenable to bypass surgery or angioplasty, or
3. Instability of fluid balance/renal function not due to patient noncompliance with regimen of weight monitoring, flexible use of diuretic drugs, and salt restriction.

III. The following conditions are inadequate indications for transplantation unless other factors as listed above are present:

1. Ejection fraction less than 20%
2. History of functional class III or IV symptoms of heart failure
3. Previous ventricular arrhythmias
4. Maximal VO\(_2\) greater than 15 mL/kg/min.

**Pediatric Patients**

1. Patients with heart failure with persistent symptoms at rest who require one or more of the following:
   - Continuous infusion of intravenous inotropic agents, or
   - Mechanical ventilatory support, or
   - Mechanical circulatory support.

2. Patients with pediatric heart disease with symptoms of heart failure who do not meet the above criteria but who have:
   - Severe limitation of exercise and activity (if measurable, such patients would have a peak maximum oxygen consumption less than 50% predicted for age and sex); or
   - Cardiomyopathies or previously repaired or palliated congenital heart disease and significant growth failure attributable to the heart disease; or
   - Near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator; or
   - Restrictive cardiomyopathy with reactive pulmonary hypertension; or
• Reactive pulmonary hypertension and potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future; or
• Anatomical and physiological conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle; or
• Anatomical and physiological conditions that may lead to consideration for heart transplantation without systemic ventricular dysfunction.

Heart retransplantation after a failed primary heart transplant may be considered medically necessary in patients who meet criteria for heart transplantation.

Heart transplantation is considered investigational in all other situations.

Policy Guidelines

Individual transplant facilities may have their own additional requirements or protocols that must be met in order for the patient to be eligible for a transplant at their facility.

Potential contraindications subject to the judgment of the transplant center:
1. Known current malignancy, including metastatic cancer
2. Recent malignancy with high risk of recurrence
3. Untreated systemic infection making immunosuppression unsafe, including chronic infection
4. Other irreversible end-stage disease not attributed to heart or lung disease
5. History of cancer with a moderate risk of recurrence
6. Systemic disease that could be exacerbated by immunosuppression
7. Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

Policy-specific potential contraindications
1. Pulmonary hypertension that is fixed as evidenced by pulmonary vascular resistance (PVR) greater than five Wood units, or trans-pulmonary gradient (TPG) greater than or equal to 16 mm/Hg despite treatment*
2. Severe pulmonary disease despite optimal medical therapy, not expected to improve with heart transplantation.*

*Some patients may be candidates for combined heart-lung transplantation (See the Heart/Lung Transplant Protocol).

Patients must meet the United Network for Organ Sharing (UNOS) guidelines for 1A, 1B, or 2 Status and not currently be Status 7.

Cardiac Specific Criteria

Specific criteria for prioritizing donor thoracic organs for transplant are provided by the Organ Procurement and Transplantation Network (OPTN) and implemented through a contract with the United Network for Organ Sharing (UNOS). Donor thoracic organs are prioritized by UNOS on the basis of recipient medical urgency, distance from donor hospital, and pediatric status. Patients who are most severely ill (Status IA) are given highest priority. Criteria from OPTN for listing status are as follows (Organ Procurement and Transplantation Network, 2015):

Adult patients (18 years of age or older)
STATUS 1A
A patient is admitted to the listing transplant center hospital and has at least one of the following devices or therapies in place:

1. Mechanical circulatory support that includes at least one of the following:
   a) Total artificial heart
   b) Intra-aortic balloon pump, or
   c) Extracorporeal membrane oxygenator (ECMO)
2. Continuous mechanical ventilation
3. Requires continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, and requires continuous hemodynamic monitoring of left ventricular filling pressures.

A patient has one of the following devices or therapies in place (with or without being admitted to the listing transplant center hospital):

1. Mechanical circulatory support that includes at least one of the following:
   a) Left ventricular assist device (LVAD)
   b) Right ventricular assist device (RVAD)
   c) Left and right ventricular assist devices (BiVAD)
2. Mechanical circulatory support and there is medical evidence of significant device-related complications including, but not limited to, thromboembolism, device infection, mechanical failure, or life-threatening ventricular arrhythmias.

STATUS 1B
A patient has at least one of the following devices or therapies in place:

1. Left ventricular assist device (LVAD)
2. Right ventricular assist device (RVAD)
3. Left and right ventricular assist devices (BiVAD)
4. Continuous infusion of intravenous inotropes

A patient that does not meet Status 1A or 1B is listed as Status 2.

Pediatric patients
A candidate listed as Status 1A meets at least one of the following criteria:

1. Requires assistance with a mechanical ventilator;
2. Requires assistance with a mechanical assist device (e.g., ECMO);
3. Requires assistance with a balloon pump;
4. Is younger than six months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level. Such a candidate may be treated with prostaglandin E (PGE) to maintain patency of the ductus arteriosus;
5. Requires infusion of a single high dose of an intravenous inotrope or multiple intravenous inotropes or multiple inotropes (e.g., addition of dopamine at greater than or equal to 5.0 µg/kg/min); or
6. Has a life expectancy without a heart transplant of less than 14 days.

A candidate listed as Status 1B meets at least one of the following criteria:

1. Requires infusion of low dose single inotropes;
2. Is younger than six months old and does not meet the criteria for Status 1A; or
3. Is in the less than 5th percentile for the candidates expected height and/or weight according to most recent Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics pediatric clinical growth chart;
4. Is 1.5 or more standard deviations below the candidate’s expected height growth or weight growth according to the most recent CDC National Center for Health Statistics pediatric clinical growth chart.

A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

Note: Pediatric heart transplant candidates who remain on the waiting list at the time of their 18th birthday without receiving a transplant continue to qualify for medical urgency status based upon the pediatric criteria.

Status 7 patients are considered temporarily unsuitable to receive a thoracic organ transplant.

Medicare Advantage

If a transplant is needed, we arrange to have the Medicare–approved transplant center review and decide whether the patient is an appropriate candidate for the transplant.

Background

In the United States, approximately 5.8 million people have heart failure and 300,000 die each year from this condition.\(^1\) The reduction of cardiac output is considered to be severe when systemic circulation cannot meet the body’s needs under minimal exertion. Heart transplantation can potentially improve both survival and quality of life in patients with end-stage heart failure.

Heart failure may be due to a number of differing etiologies, including ischemic heart disease, cardiomyopathy, or congenital heart defects. The leading indication for heart transplant has shifted over time from ischemic to nonischemic cardiomyopathy. During the period 2005 to 2010, the primary causes of heart failure in patients undergoing transplant operations were nonischemic cardiomyopathy (53%) and ischemic cardiomyopathy (38%). Approximately 3% of the heart transplants during this time period were in adults with congenital heart disease.\(^1\)

The demand for heart transplants far exceeds the availability of donor organs, and the length of time patients are on the waiting list for transplants has increased. According to data from the Organ Procurement and Transplantation Network (OPTN), in 2014, a total of 2655 heart transplants were performed in the United States.\(^2\) As of October 30, 2015, there were 4207 patients on the waiting list for a heart transplant. Also in recent years, advances in medical and device therapy for patients with advanced heart failure has improved the survival of patients awaiting heart transplantation. The chronic shortage of donor hearts has led to the prioritization of patients awaiting transplantation to ensure greater access for patients most likely to derive benefit. Prioritization criteria are issued by OPTN and fulfilled through a contract with the United Network for Organ Sharing.\(^3\)

From 2005 to 2010, approximately 3% of heart transplants were repeat transplantations.\(^1\) Heart retransplantation raises ethical issues due to the lack of sufficient donor hearts for initial transplants. UNOS does not have separate organ allocation criteria for repeat heart transplant recipients.
Regulatory Status

Heart transplantation is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA).

Related Protocols

Heart/Lung Transplant
Immune Cell Function Assay
Laboratory Tests for Heart Transplant Rejection
Total Artificial Hearts and Implantable Ventricular Assist Devices

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


