The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required and must be obtained through Case Management.** 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.

**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.

**Background**

Heart failure may be the consequence of a number of differing etiologies, including ischemic heart disease, cardiomyopathy, or congenital heart defects. The reduction of cardiac output is considered to be severe when systemic circulation cannot meet the body’s needs under minimal exertion. Heart transplantation improves quality of life and has patient survival rates at 1, 5, and 10 years of 88%, 74%, and 55%, respectively. (1)

The shortage of donor hearts has led to the use of transplantation in those most likely to derive benefit. At the same time, advances in medical and device therapy for patients with advanced heart failure has improved the survival of patients awaiting heart transplantation. Due to the variable natural history of heart failure, functional and hemodynamic parameters have been utilized to estimate prognosis.

In 2009, 2,211 heart transplants were performed in the U.S. There were 2,997 patients on the waiting list at the end of 2009. (1)

**Related Protocols:**
- Immune Cell Function Assay
- Heart-Lung Transplant
- Total Artificial Hearts and Ventricular Assist Devices

**Corporate Medical Guideline**

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, or
      - Maximal VO2 (oxygen consumption) < 10 ml/kg/min with achievement of anaerobic metabolism
- Refractory cardiogenic shock
- Documented dependence on intravenous inotropic support to maintain adequate organ perfusion

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 VO2 < 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 < 20%
2. History of functional class III or IV symptoms of heart failure
3. Previous ventricular arrhythmias
4. Maximal VO2 > 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 < 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.

Policy Guideline
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

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

*Some patients may be candidates for combined heart-lung transplantation.

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

The United Network for Organ Sharing (UNOS) prioritizes donor thoracic organs according to the severity of illness, with those patients who are most severely ill (status 1A) given highest priority in allocation of the available organ as follows: (2)

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 for acute hemodynamic decompensation that includes at least one of the following:
   • Left and/or right ventricular assist device implanted
   • Total artificial heart
   • Intra-aortic balloon pump, or
   • Extracorporeal membrane oxygenator (ECMO)
2. Mechanical circulatory support
3. Mechanical ventilation
4. Continuous infusion of inotropes and continuous monitoring of left ventricular filling pressures
5. If criteria 1, 2, 3, or 4 are not met, such status can be obtained by application to the applicable Regional Review Board.

Status 1B

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

• left and/or right ventricular device implanted, or
• 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 ventilator;
2. Requires assistance with a mechanical assist device (e.g., ECMO);
3. Requires assistance with a balloon pump;
4. A candidate 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 high dose (e.g., dobutamine ≥ 7.5 mcg/kg/min or milrinone ≥ 0.5 mcg/kg/min) or multiple inotropes (e.g., addition of dopamine at ≥ 5.0 mcg/kg/min); or

A candidate who does not meet the criteria specified in (1), (2), (3), (4), or (5) may be listed as Status 1A if the candidate has a life expectancy without a heart transplant of less than 14 days, such as due to refractory arrhythmia.

A candidate listed as Status 1B meets at least one of the following criteria:
• Requires infusion of low dose single inotropes (e.g., dobutamine or dopamine < 7.5 mcg/kg/min);
• Younger than six months old and does not meet the criteria for Status 1A; or
• Growth failure, i.e., greater than 5th percentile for weight and/or height, or loss of 1.5 standard deviations of expected growth (height or weight) based on the National Center for Health Statistics for pediatric growth curves.

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

The above clinical criteria will apply to Medicare Advantage members receiving a transplant at a Medicare approved heart transplant center. (33) Exceptions may be warranted in certain limited cases if the facility ensures safety and efficacy objectives.

Benefit Application

For all business 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.

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.


19. Auerbach SR, Richmond ME, Chen JM et al. Multiple risk factors before pediatric cardiac transplantation are associated with increased graft loss. Pediatr Cardiol 2011 [Epub ahead of print].


33. Medicare approved heart transplant centers. Available online at:

34. National Coverage Determination (NCD) for Heart Transplants (260.9).