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Medical Benefit	Effective Date: 04/01/14	Next Review Date: 01/19
Preauthorization	Yes	Review Dates: 01/10, 01/11, 01/12, 01/13, 01/14, 01/15, 01/16, 01/17, 01/18

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.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With end-stage heart failure 	Interventions of interest are: <ul style="list-style-type: none"> Heart transplant 	Comparators of interest are: <ul style="list-style-type: none"> Medical management Cardiac device-based management (e.g., left ventricular assist device, total artificial heart) 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Symptoms Morbid events Treatment-related mortality Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With a prior heart transplant complicated by graft failure or severe dysfunction of the heart 	Interventions of interest are: <ul style="list-style-type: none"> Heart retransplant 	Comparators of interest are: <ul style="list-style-type: none"> Medical management Cardiac device-based management (e.g., left ventricular assist device, total artificial heart) 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Symptoms Morbid events Treatment-related mortality Treatment-related morbidity

Description

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

Summary of Evidence

For individuals who have end-stage heart failure who receive a heart transplant, the evidence includes case series and registry data. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. Despite improvements in the prognosis for many patients with advanced heart disease, heart transplant remains a viable treatment for those with severe heart dysfunction despite appropriate medical management with medication, surgery, or medical devices. Given the exceedingly poor survival rates without transplantation for these patients, evidence of posttransplant survival is sufficient to demonstrate that heart transplantation provides a survival benefit. Heart transplantation is contraindicated in patients for whom the procedure is expected to be futile due to comorbid disease or in whom posttransplantation care is expected to worsen comorbid conditions significantly. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have had a prior heart transplant complicated by graft failure or severe dysfunction of the heart who receive a heart retransplant, the evidence includes case series and registry data. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. Despite improvements in the prognosis for many patients with graft failure, cardiac allograft vasculopathy, and severe dysfunction of the transplanted heart, heart retransplant remains a viable treatment for those who have exhausted other medical or surgical remedies, yet are still with severe symptoms. Given the exceedingly poor survival rates without retransplantation for patients who have exhausted other treatments, evidence of posttransplant survival is sufficient to demonstrate that heart retransplantation provides a survival benefit in appropriately selected patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Policy

Human heart transplantation may be considered **medically necessary** for select 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 oxygen consumption (VO_2) less than 10 mL/kg/min with achievement of anaerobic metabolism
 - Refractory cardiogenic shock
 - Documented dependence on intravenous inotropic support to maintain adequate organ perfusionor
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 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 Vo_2 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.

The factors below are 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 include:

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 s 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. The following factors are considered in assessing the severity of illness: reliance on continuous mechanical ventilation, infusion of intravenous inotropes, and/or dependency on mechanical circulatory support (i.e., total artificial heart, intra-aortic balloon pump, extracorporeal membrane oxygenator, ventricular assist device). Additional criteria, which are considered in pediatric patients, include diagnosis of an OPTN-approved congenital heart disease diagnosis, presence of ductal dependent pulmonary or systemic circulation, and diagnosis of hypertrophic or restrictive cardiomyopathy while less than one year old. Of 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 on the pediatric criteria.

Specific criteria for prioritizing donor thoracic organs for retransplant include severe coronary allograft vasculopathy, mild or moderate coronary allograft vasculopathy with a left ventricular ejection fraction less than 45%, coronary allograft vasculopathy with restrictive physiology, or symptomatic graft dysfunction without evidence of active rejection.

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

Heart Failure

In the United States, approximately 6.5 million people 20 years of age and older have heart failure and 309,000 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. From 2009 to 2014, nonischemic cardiomyopathy was the dominant underlying primary diagnosis among patients 18 to 39 years (64%) and 40 to 59 years (51%) undergoing transplant operations.² Ischemic cardiomyopathy was the dominant underlying primary diagnosis among the heart transplant recipients 60 to 69 years (50%) and 70 years and older (55%).

Overall, ischemic cardiomyopathy is the underlying heart failure diagnosis in approximately 40% of men and 20% of women who receive a transplant. Approximately 3% of the heart transplants during this time period were in adults with congenital heart disease.

Treatment

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 OPTN, in 2016, a total of 3191 heart transplants were performed in the United States.³ As of July 16, 2017, there were 3996 patients on the waiting list for a heart transplant. In recent years, innovations in medical and device therapy for patients with advanced heart failure has also 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 the OPTN and fulfilled through a contract with the UNOS.⁴

From 2008 to 2015, approximately 4% of heart transplants were repeat transplantations. Heart retransplantation raises ethical issues due to the lack of sufficient donor hearts for initial transplants. The 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.

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.

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