Heart Transplant

Description

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

Heart Failure

In the U. S., approximately 6.5 million people 20 years of age and older have heart failure and 309,000 die each year from this condition. The reduction of cardiac output is considered to be severe when systemic circulation cannot meet the body's needs under minimal exertion.

Heart failure may be due to a number of differing etiologies, including ischemic heart disease, cardiomyopathy, or congenital heart defects. The leading indication for a heart transplant has shifted over time from ischemic to non-ischemic cardiomyopathy. From 2009 to 2014, non-ischemic cardiomyopathy was the dominant underlying primary diagnosis among patients 18 to 39 years (64%) and 40 to 59 years (51%) undergoing transplant operations. 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**

Innovations in medical and device therapy for patients with advanced heart failure have improved the survival of patients awaiting heart transplantation. 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, in 2017, a total of 3244 heart transplants were performed in the U. S. As of July 2018, there were 4003 patients on the waiting list for a heart transplant. The chronic shortage of donor hearts has led to the prioritization of patients awaiting transplantation to ensure greater access for patients most likely to benefit. Prioritization criteria are issued by the Organ Procurement and Transplantation Network and fulfilled through a contract with the United Network for Organ Sharing.

From 2008 to 2015, approximately 4% of heart transplants were repeated transplantations. Heart retransplantation raises ethical issues due to the lack of sufficient donor hearts for initial transplants. The United Network for Organ Sharing does not have separate organ allocation criteria for repeat heart transplant recipients.

**Prioritization of Candidates**

Most heart transplant recipients now are hospitalized as status 1 patients at the time of transplant. This shift has occurred due to the increasing demand for the scarce resource of donor organs resulting in increased waiting time for recipients. Patients initially listed as status 2 candidates may deteriorate to a status 1 candidate before a donor organ becomes available. Alternatively, as medical and device therapy for advanced heart failure improves, some patients on the transplant list will recover enough function to be delisted. Lietz and Miller (2007) reported on survival for patients on the heart transplant waiting list, comparing the era between 1990 and 1994 with the era of 2000 to 2005. One-year survival for United Network for Organ Sharing status 1 candidate improved from 49.5% to 69.0%. Status 2 candidates fared even better, with 89.4% surviving 1 year compared with 81.8% in the earlier time period.

Johnson et al (2010) reported on waiting list trends in the U. S. between 1999 and 2008. The proportion of patients listed as status 1 increased, even as the waiting list and post-transplant mortality for this group have decreased. Meanwhile, status 2 patients have decreased as a proportion of all candidates. Completed transplants have trended toward the extremes of age, with more infants and patients older than age 65 years having transplants in recent years.

As a consequence, aggressive treatment of heart failure has been emphasized in recent guidelines. Prognostic criteria have been investigated to identify patients who have truly exhausted medical therapy and thus are likely to derive the maximum benefit for heart transplantation. Maximal oxygen consumption (VO₂max), which is measured during maximal exercise, is a measure suggested as a critical objective criterion of the functional reserve of the heart. The American College of Cardiology and American Heart Association have adopted VO₂max as a criterion for patient selection. Studies have suggested that transplantation can be safely deferred in those patients with a VO₂max of greater than 14 mL/kg/min. The importance of the VO₂max has also been emphasized by the American Heart Association when addressing heart transplant candidacy. In past years, a left ventricular ejection fraction of less than 20% or a New York Heart Association class III or IV status might have been used to determine transplant candidacy. However, as indicated by the American College of Cardiology criteria, these measurements are no longer considered adequate to identify transplant candidates. These measurements may be used to identify patients for further cardiovascular workup but should not be the sole criteria for transplant.

Methods other than VO₂max have been proposed as predictive models in adults. The Heart Failure Survival Scale and the Seattle Heart Failure Model (SHFM) are examples. In particular, the SHFM provides an estimate of 1-, 2-, and 3-year survival with the use of routinely obtained clinical and laboratory data. Information on pharmacologic and device usage is incorporated into the model, permitting some estimation on the effects of current, more aggressive heart failure treatment strategies. Levy et al (2006) introduced the model using a multivariate analysis of data from the Prospective Randomized Amlodipine Survival Evaluation-1 heart failure trial (n=1125). SHFM has been validated in both ambulatory and hospitalized heart failure populations, but with a noted underestimation of mortality risk, particularly in blacks and device recipients. None of these models has been universally adopted by transplant centers.
**OBJECTIVE**

The objective of this evidence review is to determine whether heart transplantation or retransplantation improves the net health outcome in patients with end-stage heart failure.

**POLICY STATEMENT**

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

**Adult Patients**

1. **Accepted Indications for Cardiac Transplantation**
   1. Hemodynamic compromise due to heart failure demonstrated by any of the following 3 bulleted items,
      - Maximal oxygen consumption ($V_{O_2}$) $<10$ mL/kg/min with achievement of anaerobic metabolism; or
      - Refractory cardiogenic shock; or
      - 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.

2. **Probable Indications for Cardiac Transplantation**
   1. Maximal $V_{O_2} < 14$ 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.

3. The following conditions are inadequate indications for cardiac 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 $V_{O_2} > 15$ mL/kg/min.

**Pediatric Patients**

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

2. Patients with heart disease and 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 maximum $V_{O_2} < 50\%$ 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 risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future; or
   - Anatomic and physiologic conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle; or
   - Anatomic and physiologic 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.

---

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
Heart transplantation is considered **investigational** in all other situations.

**POLICY GUIDELINES**

**General Criteria**

Potential contraindications for solid organ transplant are subject to the judgment of the transplant center include the following:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage diseases not attributed to heart or lung disease
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

Policy-specific potential contraindications include:

- Pulmonary hypertension that is fixed as evidenced by pulmonary vascular resistance > 5 Wood units, or transpulmonary gradient ≥ 16 mm/Hg despite treatment
- Severe pulmonary disease, despite optimal medical therapy, not expected to improve with heart transplantation

*Some patients may be candidates for combined heart and lung transplantation (see evidence review 7.03.08).*

Patients must meet the United Network for Organ Sharing (UNOS) guidelines for status 1A, 1B, or 2 (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 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 1A) are given the 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 1 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.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

While patients listed as status 1 are considered clear candidates for a heart transplant, Plans may want to consider a medical review of those patients listed as status 2 to determine whether patients meet the acceptable or probable indications for a heart transplant. Transplant centers may vary in their adherence to these criteria.
FDA REGULATORY STATUS

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

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation Title 21, parts 1270 and 1271. Heart transplants are included in these regulations.

RATIONALE

Summary of Evidence

For individuals who have end-stage heart failure who receive a heart transplant, the evidence includes case series and registry data. The relevant outcomes are overall survival (OS), symptoms, morbid events, and treatment-related morbidity and mortality. 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 post-transplant survival is sufficient to demonstrate that heart transplantation provides a survival benefit. Heart transplantation is contraindicated for patients for whom the procedure is expected to be futile due to comorbid disease or for whom post-transplantation 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. The relevant outcomes are OS, 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 whose severe symptoms persist despite treatment with other medical or surgical remedies. Given the exceedingly poor survival rates without retransplantation for patients who have exhausted other treatments, evidence of post-transplant 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Cardiology Foundation and American Heart Association

Guidelines from the American College of Cardiology Foundation and the American Heart Association were updated in 2017. Evaluation for heart transplantation was recommended for patients in whom heart failure is assessed as refractory based on New York Heart Association functional class III or IV (stage D) for heart failure after previous guideline-directed medical therapy, use of devices such as an implantable cardioverter-defibrillator or a cardiac resynchronization therapy device, or surgical management.
The International Society for Heart and Lung Transplantation (ISHLT; 2004) has recommended that children with the following conditions be evaluated for heart transplantation (see Table 1).

### Table 1. Recommendations for Pediatric Heart Transplant

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diastolic dysfunction that is refractory to optimal medical/surgical management because they are at high risk of developing pulmonary hypertension and of sudden death</td>
<td>B</td>
</tr>
<tr>
<td>Advanced systemic right ventricular failure (Heart Failure Stage C described as patients with underlying structural or functional heart disease and past or current symptoms of heart failure) that is refractory to medical therapy</td>
<td>C</td>
</tr>
</tbody>
</table>

LOE B is based on a single randomized trial or multiple nonrandomized trials; LOE C is based primarily on expert consensus opinion.

LOE: level of evidence.

ISHLT (2016) published a 10-year update to its listing criteria for heart transplantation. The guidelines recommended the following updates or changes to the 2006 guideline:

- Recommended use of heart failure prognosis scores (eg, Seattle Heart Failure Model, Heart Failure Survival Score) along with cardiopulmonary exercise test to determine prognosis and guide listing for transplantation for ambulatory patients.
- Periodic right heart catheterization for routine surveillance was not recommended in children.
- Carefully selected patients >70 years of age may be considered for cardiac transplantation.
- Pre-existing neoplasm, body mass index of ≥ 35 kg/m², diabetes with "end-organ damage (other than non-proliferative retinopathy) or poor glycemic control ... despite optimal effort," irreversible renal dysfunction, clinically severe symptomatic cerebrovascular disease, peripheral vascular disease, and frailty are considered relative contraindications to heart transplantation.
- Considering active smoking during the previous 6 months as a risk factor for poor outcomes after transplantation, active tobacco smoking is considered a relative contraindication for heart transplantation. Similarly, patients who remain active substance abusers (including alcohol) are not recommended to receive heart transplantation.

This same ISHLT (2016) guidelines update states the following regarding retransplantation indications:

"Retransplantation is indicated for those patients who develop significant CAV [(cardiac allograft vasculopathy)] with refractory cardiac allograft dysfunction, without evidence of ongoing acute rejection (Class IIa, Level of Evidence: C)."

The guidelines cite the published consensus by Johnson et al (2007) on indications for retransplantation. It states that based on available data, appropriate indications for retransplantation include "the development of chronic severe CAV with symptoms of ischemia or heart failure, CAV without symptoms but with moderate to severe LV [(left ventricle)] dysfunction, or symptomatic graft dysfunction without evidence of active rejection." Retransplantation within the first six months after previous transplantation, especially with immunologic complications as a primary cause, was considered high-risk.

As a note on heart transplantation in children, the 2016 guidelines update states, "although nearly half of all HTs [(heart transplants)] in children are done for CHD [(congenital heart disease)],... it should be noted that general considerations vary for more traditional indications, such as idiopathic dilated cardiomyopathy, for transplantation in the pediatric population....Thus, as these guidelines are translated to the younger patient, such prudence will need to be exercised."
The guidelines from ISHLT (2010) on the care of heart transplant recipients include the following recommendations on cardiac retransplantation:

- "Retransplantation is indicated in children with at least moderate systolic heart allograft dysfunction and/or severe diastolic dysfunction and at least moderate CAV (cardiac allograft vasculopathy)."
- "It is reasonable to consider listing for retransplantation those adult HT [heart transplant] recipients who develop severe CAV not amenable to medical or surgical therapy and symptoms of heart failure or ischemia."
- "It is reasonable to consider listing for retransplantation those HT recipients with heart allograft dysfunction and symptomatic heart failure occurring in the absence of acute rejection."
- "It is reasonable to consider retransplantation in children with normal heart allograft function and severe CAV."

American Heart Association

The American Heart Association (2007) indicated that, based on level B (nonrandomized studies) or level C (consensus opinion of experts) evidence, heart transplantation is indicated for pediatric patients as therapy for the following indications:

- Stage D heart failure (interpreted as abnormal cardiac structure and/or function, continuous infusion of intravenous inotropes, or prostaglandin E₁ to maintain patency of a ductus arteriosus, mechanical ventilatory and/or mechanical circulatory support) associated with systemic ventricular dysfunction in patients with cardiomyopathies or previous repaired or palliated congenital heart disease.
- Stage C heart failure (interpreted as abnormal cardiac structure and/or function and past or present symptoms of heart failure) associated with pediatric heart disease and severe limitation of exercise and activity, in patients with cardiomyopathies or previously repaired or palliated congenital heart disease and heart failure associated with significant growth failure attributed to heart disease, pediatric heart disease with associated near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator, or in pediatric restrictive cardiomyopathy disease associated with reactive pulmonary hypertension;
- The guidelines state that heart transplantation is feasible in the presence of other indications for heart transplantation, “in patients with pediatric heart disease and an elevated pulmonary vascular resistance index >6 Woods units/m² and/or a transpulmonary pressure gradient >15 mm Hg if administration of inotropic support or pulmonary vasodilators can decrease pulmonary vascular resistance to <6 Woods units/m² or the transpulmonary gradient to <15 mm Hg."

European Society of Cardiology

The European Society of Cardiology (2016) guidelines on the diagnosis and treatment of acute and chronic heart failure recommended considering heart transplantation for patients with end-stage heart failure with severe symptoms, poor prognosis, and no alternative treatment options. Active infection, severe peripheral arterial or cerebrovascular ischemia, pharmacologically irreversible pulmonary hypertension, cancer, renal insufficiency, systemic disease with multorgan involvement, pretransplant body mass index greater than 35 kg/m², current alcohol or drug abuse, and insufficient social support to achieve compliant care in the outpatient setting were considered relative contraindications for heart transplantation.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Cardiac transplantation is covered under Medicare when performed in a facility approved by Medicare. The Centers for Medicare & Medicaid Services has stated that, under certain limited cases, exceptions to the criteria may be warranted if there is justification and if

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
the facility ensures safety and efficacy objectives.

REFERENCES


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.


60. Canter CE, Shaddy RE, Bernstein D, et al. Indications for heart transplantation in pediatric heart disease: a scientific statement from the American Heart Association Council on Cardiovascular Disease in the Young; the Councils on Clinical Cardiology, Cardiovascular Nursing, and Cardiovascular Surgery and Anesthesia; and the Quality of Care and Outcomes Research Interdisciplinary Working Group. Circulation. Feb 6 2007;115(5):658-676. PMID 17261651


**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2012</td>
<td>New policy</td>
<td></td>
</tr>
<tr>
<td>March 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review. No change to policy statement.</td>
</tr>
<tr>
<td>March 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature search. Policy statement on re-transplantation added and all other indications are considered investigational.</td>
</tr>
<tr>
<td>March 2015</td>
<td>Replace policy</td>
<td>Policy was updated with a literature review through September 2014, adding references 21, 25, and 28. Policy statements are unchanged.</td>
</tr>
<tr>
<td>March 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review through October 7, 2015; references 18, 21, 29, 36, 38, and 48 added. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 7, 2018; references 42, 51, and 56 added; reference 4 updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>December 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 10, 2019; no references added. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.