Solid Organ Transplants

BCBSA Ref. Policies: 7.03.02, 7.03.06, 7.03.07 & 7.03.09

Effective Date: March 1, 2017
Last Revised: July 27, 2018
Replaces: 7.03.500, 7.03.502; 7.03.503, 7.03.504, 7.03.505, 7.03.506

Related Medical Policies:
- 7.03.11 Percutaneous Ventricular Assist Devices
- 7.03.04 Intestinal and Multivisceral Organ Transplant Surgery
- 8.03.05 Transcatheter Arterial Chemoembolization as a Treatment for Primary or Metastatic Liver Malignancies
- 8.03.05 Outpatient Pulmonary Rehabilitation

Introduction

An organ transplant is the surgical process of replacing a severely diseased organ with a healthy one from a donor. The donated organ can come from a living person or a person who passed away from an accident or illness. Organ failure is the most common reason a transplant is needed. Organ failure can occur because of illness, injury, or birth defect. There are many factors that go into finding a donor organ that matches. These include blood type and the size of the organ. Other factors include how long a person has been on the waiting list, the level of illness, and the distance the donated organ must be transported. This policy describes when transplanting a solid organ may be considered medically necessary. This policy notes that a plan physician will review solid organ transplant requests together with the criteria of the transplant center.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
## Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Transplant</th>
<th>Medical Necessity</th>
</tr>
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</table>
| **Heart transplant** | A human heart transplant may be considered medically necessary for patients with end-stage heart failure. “End stage heart failure” commonly reflects New York classification stage 3 or 4. (These are functional classifications, but describe scenarios that patients will be unlikely to return to normal level of function without some fundamental change in their physiology, and because of the dysfunction of the organ system in question, other organ systems are showing signs of deterioration.)  
Heart retransplantation after a failed primary heart transplant may be considered medically necessary in patients who meet criteria for heart transplantation.  
Heart transplants that require concurrent coronary artery bypass graft surgery of the donor heart are considered investigational. |
| **Heart/lung transplant** | A combined heart/Lung transplant may be considered medically necessary for patients with end-stage cardiac and end-stage pulmonary disease.  
Heart/lung retransplantation after a failed primary heart/lung transplant may be considered medically necessary in patients who meet criteria for heart/lung transplantation. |
| **Kidney transplant** | Kidney transplants, using a deceased (cadaver) or living donor, may be considered medically necessary for patients who have documented end-stage renal disease or imminent end-stage renal disease.  
Kidney retransplant after a failed primary kidney transplant may be considered medically necessary. |
<p>| <strong>Liver transplant</strong> | Liver transplants, using a deceased (cadaver) or living donor, may be considered medically necessary for patients with end- |</p>
<table>
<thead>
<tr>
<th>Transplant</th>
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<tbody>
<tr>
<td>Lung transplant and lobar lung transplant</td>
<td>Lung transplants may be considered medically necessary for patients with end-stage pulmonary disease.</td>
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<td>Lobar lung transplants from a living or deceased donor may be considered medically necessary for patients including children and adolescents with end-stage pulmonary disease.</td>
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<tr>
<td>Pancreas transplant</td>
<td>Pancreas transplant after a prior kidney transplant may be considered medically necessary in patients with insulin dependent diabetes.</td>
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<td>A pancreas transplant alone may be considered medically necessary in patients with severely disabling and potentially life-threatening complications due to hypoglycemia unawareness and labile insulin dependent diabetes.</td>
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<td>Pancreas retransplants after a failed primary pancreas transplant may be considered medically necessary.</td>
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<td></td>
<td>Pancreas retransplant after two or more prior failed pancreas transplants is considered investigational.</td>
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<tr>
<td>Pancreas/kidney transplant</td>
<td>A combined pancreas/kidney transplant may be considered medically necessary in insulin-dependent diabetic patients.</td>
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<tr>
<td>Transplant</td>
<td>Investigational</td>
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<tr>
<td>Solid organ transplants (other)</td>
<td>Solid organ transplants other than those addressed above are considered investigational (see Related Policies).</td>
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</table>

A Company Medical Director or his/her designee will review all solid organ transplants for medical necessity in conjunction with the criteria of the Transplant Center.

If the member meets the criteria of the Transplant Center, the transplant may be considered medically necessary.
### Coding

<table>
<thead>
<tr>
<th>Code</th>
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<tbody>
<tr>
<td><strong>CPT</strong></td>
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<tr>
<td>32851</td>
<td>Lung transplant, single; without cardiopulmonary bypass</td>
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<tr>
<td>32852</td>
<td>Lung transplant, single; with cardiopulmonary bypass</td>
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<tr>
<td>32853</td>
<td>Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass</td>
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<tr>
<td>32854</td>
<td>Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass</td>
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<tr>
<td>33935</td>
<td>Heart-lung transplant with recipient cardiectomy-pneumonectomy</td>
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<tr>
<td>33945</td>
<td>Heart transplant, with or without recipient cardiectomy</td>
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<tr>
<td>47135</td>
<td>Liver allotransplantation, orthotopic, partial or whole, from cadaver or living donor, any age</td>
</tr>
<tr>
<td>47136</td>
<td>Liver allotransplantation; heterotopic, partial or whole, from cadaver or living donor, any age (Code deleted effective 01/01/16, replaced with 47399)</td>
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<tr>
<td>47399</td>
<td>Unlisted procedure, liver</td>
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<tr>
<td>48554</td>
<td>Transplantation of pancreatic allograft</td>
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<td>50360</td>
<td>Renal allotransplantation, implantation of graft; without recipient nephrectomy</td>
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<tr>
<td>50365</td>
<td>Renal allotransplantation, implantation of graft; with recipient nephrectomy</td>
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<td><strong>HCPCS</strong></td>
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<tr>
<td>S2060</td>
<td>Lobar lung transplantation</td>
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<td>S2065</td>
<td>Simultaneous pancreas kidney transplantation</td>
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<tr>
<td>S2152</td>
<td>Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre and posttransplant care in the global definition</td>
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</tbody>
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Related Information

Benefit Application

See health plan contract language for organ transplant benefits; there may be contract limitations on transplants (see Scope). This policy does not apply to Medicare Advantage.

Evidence Review

Description

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

For purposes of this medical policy, solid organ transplants include heart, heart/lung, kidney, liver, lung, lobar lung, pancreas and pancreas/kidney transplants.

Small bowel, small bowel/liver and multivisceral transplants are addressed in a separate medical policy (see Related Policies).

Summary of Evidence

Heart Transplant

The evidence for the use of heart transplant in individuals with end stage heart failure includes case series and registry data. Relevant outcomes include overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. Given the exceedingly poor survival of patients who have exhausted other treatments, evidence of post-transplant survival is sufficient to demonstrate that heart transplantation provides a survival benefit in appropriately selected patients. 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. Heart transplantation is contraindicated in patients in whom the procedure 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.

**Heart/Lung Transplant**

The evidence for combined heart-lung transplant in individuals who have end-stage cardiac and pulmonary disease includes case series and registry data. Relevant outcomes include overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. The available literature, consisting of case series and registry data, describes outcomes after heart/lung transplantation. Given the exceedingly poor expected survival without transplantation, this evidence is sufficient to demonstrate that heart/lung transplantation provides a survival benefit in appropriately selected patients. It may be the only option for some patients with end-stage cardiopulmonary disease.

Heart/lung transplant is contraindicated in patients in whom the procedure is expected to be futile due to comorbid disease or in whom post-transplantation care is expected to significantly worsen comorbid conditions. Based on this evidence and established guidelines, heart/lung transplant may be considered medically necessary for those who meet clinical criteria and do not have contraindications to the procedure. A very limited amount of data suggest that, after controlling for confounding variables, survival rates after primary and repeat heart/lung transplants is similar. Findings are not conclusive due to the small number of cases of repeat heart/lung transplants reported in the published literature. Repeat heart/lung transplantation may be considered medically necessary in patients with a failed prior transplant who meet the clinical criteria for heart/lung transplantation.

**Kidney Transplant**

For individuals who have ESRD without contraindications to kidney transplant who receive a kidney transplant from a living donor or deceased (cadaveric) donor, the evidence includes registry data and case series. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Data from large registries have demonstrated a reasonably high survival rate after kidney transplant for appropriately selected patients and significantly higher survival rates for patients undergoing kidney transplant compared with those who remained on a waiting list. Kidney transplantation is contraindicated for 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. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a failed kidney transplant without contraindications to kidney transplant who receive kidney retransplant from a living donor or deceased (cadaveric) donor, the evidence includes registry data and case series. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Data have demonstrated a reasonably high survival rate after kidney retransplant for appropriately selected patients (eg, 5-year patient survival rates ranging from 87% to 96%). Kidney retransplantation is contraindicated for 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. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Liver Transplantation

Liver transplant is an accepted treatment of end-stage liver disease that provides a survival benefit in appropriately selected patients and thus, may be considered medically necessary for the indications listed in the Policy Statement and in those otherwise meeting United Network of Organ Sharing (UNOS) criteria. Liver transplantation is investigational 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. Case series and case-control data indicate that HIV infection is not an absolute contraindication to liver transplant; for patients who meet selection criteria, these studies have demonstrated patient and graft survival rates are similar to those in the general population of liver transplant recipients.

Recent literature continues to address expanded criteria for transplantation for hepatocellular carcinoma (HCC), predictors of recurrence, the role of neoadjuvant therapy in patients with HCC, expanded donor criteria, transplantation and retransplantation for hepatitis C, and living donor transplantation. Further study is needed before liver transplant selection criteria can be expanded for HCC. Additionally, further study is needed to address salvage liver transplantation for HCC recurrence after primary liver resection.

Liver transplantation for hilar cholangiocarcinoma is performed at some transplant centers, and long-term survival has been reported in select patients with unresectable disease. For metastatic neuroendocrine tumors (NET), cure of disease is not achieved, and 5-year survival is generally not high. However, there have been reports of survival benefit in patients receiving liver transplantation for unresectable neuroendocrine tumor metastasis confined to the liver. Based
on survival data and clinical vetting input, transplantation in patients with hilar cholangiocarcinoma who meet strict eligibility criteria may be considered medically necessary; transplantation for NET metastatic to the liver is considered investigational.

The literature on liver transplantation for pediatric hepatoblastoma is limited, but case series have demonstrated good outcomes and high rates of long-term survival. Additionally, nonmetastatic pediatric hepatoblastoma is included in UNOS criteria for patients eligible for liver transplantation. Therefore, liver transplantation for nonmetastatic pediatric hepatoblastoma may be considered medically necessary.

Case series have demonstrated favorable outcomes with liver retransplantation in certain populations, such as when criteria for an original liver transplantation are met for retransplantation. While some evidence suggests outcomes after retransplantation may be less favorable than for initial transplantation in some patients, long-term survival benefits have been demonstrated. There was support from clinical vetting for retransplantation following primary graft nonfunction, hepatic artery thrombosis, chronic rejection, or certain recurrent nonneoplastic diseases resulting in end-stage liver failure in the primary transplant. As a result, retransplantation after initial failed liver transplant may be considered medically necessary in these situations.

**Lung and Lobar Lung Transplantation**

The literature on lung and lobar lung transplantation, which consists of case series and registry data, demonstrates that lung and lobar lung transplantation provides a survival benefit in appropriately selected patients and thus may be considered medically necessary. It may be the only option for some patients with end-stage lung disease.

The literature on lung retransplantation is limited but is accumulating in registry data. As in lung transplantation, lung retransplantation may be the only option for patients with failed lung transplantation.

**Pancreas Transplant**

The literature, consisting primarily of case series and registry data, demonstrate graft survival rates comparable with other solid organ transplants, as well as attendant risks associated with the immunosuppressive therapy necessary to prevent allograft rejection. No randomized controlled trials have compared any form of pancreas transplant with insulin therapy. Pancreas
transplant may be considered medically necessary in patients with insulin dependent diabetes who are undergoing, or have undergone, kidney transplantation for renal failure. It may also be considered medically necessary as a stand-alone treatment in patients with hypoglycemia unawareness and labile diabetes, despite optimal medical therapy and in whom severe complications have developed.

Ongoing and Unpublished Clinical Trials

Clinical Trials for Liver Transplant

NCT00301379 Washington State University is conducting a prospective registry study of neoadjuvant chemoradiation in conjunction with liver transplantation for cholangiocarcinoma. There is an estimated enrollment of 20 and an estimated completion date of November 2015.

NCT01549795 A study on liver transplantation for hilar cholangiocarcinoma began in March 2012 in Italy. This study will enroll 33 patients, is still recruiting and had a primary completion date of July 2013. Status of this study is unknown, last verified in July 2012.

NCT01201096 Liver transplantation for metastatic NET is being evaluated in a German study. In this observational study, patients will receive neoadjuvant peptide receptor-mediated radiotherapy with 177 lutetium about 9 months prior to liver transplantation. This study is expected to enroll 50 patients and is scheduled for completion in September 2018. This study was last verified in September 2010.

NCT01387503 A study on liver transplantation after downstaging HCC exceeding the Milan Criteria is ongoing in Italy. This study is evaluating 260 patients and is expected to be completed in January 2014. The status of this study is unknown, last verified in June 2011.

Clinical Trials for Pancreas Transplant

NCT01067950 The Pancreas Allotransplantation for Diabetic Nephropathy and Mild Chronic Renal Failure Stage (PANCREAS) Study is currently recruiting participants at Nantes University in France. The stated objective of the open-label RCT study is to assess the superiority of isolated pancreas transplant to intensive insulin therapy in Type 1 diabetes patients with overt proteinuric nephropathy and mildly reduced renal function. The primary combined endpoint is to be patient mortality and renal function impairment at five years. If completed, this would
represent the first RCT comparing pancreas transplant to insulin therapy. The study was scheduled to start in 2010; no updates are available as of December 2014.

Practice Guidelines and Position Statements

Heart Transplant

American College of Cardiology (ACC)/American Heart Association (AHA)

Guidelines from the American College of Cardiology (ACC) and American Heart Association (AHA) on the diagnosis and management of chronic heart failure, updated in 2005 and then in 2009, provide statements about the accepted indications, probable indications, and contraindications for heart transplantation.6

Adult Patients

Accepted Indications for Transplantation

• Hemodynamic compromise due to heart failure demonstrated by any of the following 3 bulleted items,
  o Maximal VO2 (oxygen consumption) <10 mL/kg/min with achievement of anaerobic metabolism
  o Refractory cardiogenic shock
  o Documented dependence on intravenous inotropic support to maintain adequate organ perfusion, or

• Severe ischemia consistently limiting routine activity not amenable to bypass surgery or angioplasty, or

• Recurrent symptomatic ventricular arrhythmias refractory to ALL accepted therapeutic modalities.

Probable Indications for Cardiac Transplantation

• Maximal VO2 <14 mL/kg/min and major limitation of the patient’s activities, or

• Recurrent unstable ischemia not amenable to bypass surgery or angioplasty, or
- Instability of fluid balance/renal function not due to patient noncompliance with a regimen of weight
- Monitoring, flexible use of diuretic drugs, and salt restriction

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

- Ejection fraction <20%
- History of functional class III or IV symptoms of heart failure
- Previous ventricular arrhythmias
- Maximal VO2 >15 mL/kg/min

**Pediatric Patients**

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

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

**International Society for Heart and Lung Transplantation (ISHLT)- Pediatric**

In a 2004 statement, International Society for Heart and Lung Transplantation (ISHLT) recommended that children with the following conditions should be evaluated for heart transplantation\(^{171}\):

• Diastolic dysfunction that is refractory to optimal medical/surgical management because they are at high risk of developing pulmonary hypertension and of sudden death (based on level of evidence B [a single randomized trial or multiple nonrandomized trials]).

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 (level of evidence C [primarily expert consensus opinion]).

In 2014, the ISHLT issued updated guidelines on the management of pediatric heart failure.\(^{196}\) These guidelines do not provide updated guidance about transplantation listing because the IHSLT was in the process of updating its overall guidance about heart transplantation listing criteria.

**International Society for Heart and Lung Transplantation (ISHLT) – Potential Contraindications**

ISHLT’s 2006 Guidelines for the Care of Cardiac Transplant Candidates included the following statements on potential contraindications to heart transplantation\(^{172}\):

• “Patients should be considered for cardiac transplantation if they are ≤70 years of age.”
  “Carefully selected patients >70 years of age may be considered for cardiac transplantation.”
• For patients with preexisting neoplasms, “cardiac transplantation should be considered when tumor recurrence is low based on tumor type, response to therapy and negative metastatic work-up.”

• For obese patients, “it is reasonable to recommend weight loss to achieve a BMI of <30 kg/m2 or percent BMI of <140% of target before listing for cardiac transplantation.”

• “Diabetes with end-organ damage other than nonproliferative retinopathy or poor glycemic control (glycosylated hemoglobin [HbA1C] >7.5) despite optimal effort is a relative contraindication for transplant.”

• “It is reasonable to consider the presence of irreversible renal dysfunction (eGFR <40 mL/min) as a relative contraindication for heart transplantation alone.”

• “Peripheral vascular disease may be considered as a relative contraindication for transplantation when its presence limits rehabilitation and revascularization is not a viable option.”

• “It is reasonable to consider active tobacco smoking as a relative contraindication to transplantation. Active tobacco smoking during the previous 6 months is a risk factor for poor outcomes after transplantation.”

• “A structured rehabilitative program may be considered for patients with a recent (24 months) history of alcohol abuse if transplantation is being considered.... Patients who remain active substance abusers (including alcohol) should not receive heart transplantation.”

• “Mental retardation or dementia may be regarded as a relative contraindication to transplantation.” (Level of Evidence: C).

• “Patients who have demonstrated an inability to comply with drug therapy on multiple occasions should not receive transplantation.”

The AHA Council on Cardiovascular Disease in the Young

The AHA 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 stated in 2007 that, based on level B (nonrandomized studies) or level C (consensus opinion of experts), heart transplantation is indicated for pediatric patients as therapy for the following indications\textsuperscript{173}:
• 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 guideline states 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.

International Society for Heart and Lung Transplantation (ISHLT) - Cardiac Retransplantation

The 2010 guidelines from the ISHLT 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.”

Heart/Lung Transplant

International Society for Heart and Lung Transplantation (IHS\LT)


For combined heart-lung transplant, the guidelines state:

• “Most commonly, patients with irreversible myocardial dysfunction or congenital defects with irreparable defects of the valves or chambers in conjunction with intrinsic lung disease or severe PAH [pulmonary arterial hypertension] are considered for heart-lung transplantation.

• “PAH and elevated PVR [pulmonary vascular resistance], defined as a PVR > 5 Woods units, a PVR index > 6, or a transpulmonary pressure gradient 16 to 20 mm Hg, should be considered as relative contraindications to isolated cardiac transplantation. If the pulmonary artery systolic pressure is >60 mm Hg in conjunction with any of these 3 variables, the risk of right heart failure and early death is increased.

• “If the PVR can be reduced to <2.5 with a vasodilator but the systolic blood pressure falls to <85 mm Hg, the patient remains at high risk of right heart failure and mortality after isolated cardiac transplantation. Mechanical circulatory support may be considered to improve these indices and still enable cardiac transplantation and obviate the need for heart-lung transplantation.

• “In most patients with pulmonary hypertension associated with right ventricular failure, isolated bilateral lung transplantation is associated with comparable or better results than heart-lung transplantation.”
**Kidney Transplant**

**European Renal Best Practice**

In 2016, the European Renal Best Practice advisory group published guidance on managing older patients (age >65 years) with chronic kidney disease stage 3b or higher (estimated glomerular filtration rate [eGFR] <45 mL/min/1.73 m²). One of the clinical questions in the guidance involved the criteria and appropriateness of transplantation in older patients with end stage renal failure. Because older patients are often excluded from trials, evidence is limited and the panel issued a separate narrative on the topic. The position statement asserted that patients should not be deemed ineligible for renal transplantation based on age alone, and that for select elderly patients, transplantation is superior to dialysis in increasing survival. Before elderly patients should be considered for transplantation, psychological testing and assessments of comorbidities (in particular, cardiac evaluation and malignancy testing) should be performed.

**British Transplantation Society**

In 2014, the British Transplantation Society published a guideline on the management of the failed kidney transplant. Among other recommendations, the guideline stated that appropriate patients with failing kidney transplants can undergo retransplantation when the graft eGFR falls to 10 to 15 mL/min. In addition, the guideline included a suggestion that joint transplant or advanced kidney care be initiated at least 6 to 12 months before the expected need for dialysis or retransplantation, or when the eGFR is less than 20 mL/min. The authors noted that these recommendations were based on low-quality evidence.

**American Society of Transplant Surgeons et al**

In 2011, the American Society of Transplant Surgeons, American Society of Transplantation, Association of Organ Procurement Organizations, and the United Network for Organ Sharing issued a position statement recommending the modification of the National Organ Transplant Act of 1984. Their recommendation was that the potential pool of organs from HIV-infected donors be explored. With modern antiretroviral therapy, the use of these previously banned organs would open an additional pool of donors to HIV-infected recipients. The increased pool of donors has the potential to shorten waiting times for organs and decrease the number of waiting list deaths. The organs from HIV infected deceased donors would be used for transplant only with patients already infected with HIV. In 2013 the HIV Organ Policy Equity (HOPE) Act was passed allowing the use of this group of organ donors.
British HIV Association and the British Transplantation Society

In 2006, the British HIV Association and the British Transplantation Society Standards Committee published guidelines for kidney transplantation in patients with HIV disease. The guidelines recommend that any patient with end stage renal disease with a life expectancy of at least 5 years is considered appropriate for transplantation under the following conditions:

- CD4 >200 cells/mL for at least 6 months
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months
- Demonstrable adherence and a stable HAART [highly active antiretroviral therapy] regimen for at least 6 months
- Absence of AIDS-defining illness following successful immune reconstitution after HAART.

The document lists general and disease-specific exclusion criteria and immunosuppressant protocols. These recommendations are based on level III evidence (observational studies and case reports).

Liver Transplant

Multiple Professional Society Position Statement

In December 2010, 10 international liver diseases or transplantation societies held an international consensus conference on liver transplantation for HCC. Consensus criteria for selecting candidates for liver transplantation were developed at the conference. Milan criteria was recommended for use as the benchmark for patient selection, although it is noted the Milan criteria may be modestly expanded based on data from expansion studies that demonstrate outcomes that are comparable to outcomes from studies using the Milan criteria. Candidates for liver transplantation should also have a predicted survival of 5 years or more. The consensus criteria indicate alpha-fetoprotein concentrations may be used with imaging to assist in determining patient prognosis.

In regard to liver retransplantation, the consensus criteria issued a weak recommendation indicating retransplantation after graft failure of a living donor transplant for HCC is acceptable in patients meeting regional criteria for a deceased donor liver transplant. A strong recommendation was issued indicating liver retransplantation with a deceased donor for graft failure for patients exceeding regional criteria is not recommended. And the consensus criteria
issued a strong recommendation that liver retransplantation for recurrent HCC is not appropriate. However, a de novo HCC may be treated as a new tumor and retransplantation may be considered even though data to support this are limited.

American Association for the Study of Liver Diseases (AASLD)

In 2005, the American Association for the Study of Liver Diseases (AASLD) issued guidelines on evaluating patients for liver transplant. These guidelines state liver transplantation is indicated for acute or chronic liver failure from any cause after all effective medical treatments have been attempted. Furthermore, AASLD guidelines indicate patients should be assessed by a transplantation center to determine whether liver transplantation is appropriate. While AASLD guidelines indicate liver transplant may be appropriate in patients with cholangiocarcinoma and metastatic neuroendocrine tumors, these recommendations and many of the recommendations in AASLD guidelines are based on opinion.

The European Neuroendocrine Society (ENETS)

The European Neuroendocrine Society (ENETS) issued consensus guidelines in 2008 and updated in 2012 for the management of patients with liver metastases from neuroendocrine tumors. ENETS guidelines indicate, in a “minimal consensus” statement, that liver transplantation may be considered for diffuse unresectable neuroendocrine tumor metastases or when hormonal disturbances that are refractory to medical therapy are life-threatening.

National Comprehensive Cancer Network (NCCN)

The National Comprehensive Cancer Network (NCCN) guidelines on hepatobiliary cancers V1.2015 recommends referral to a liver transplant center or bridge therapy for patients with HCC meeting UNOS criteria of a single tumor 5 cm or less, or 2 to 3 tumors 3 cm or less with no macrovascular involvement or extrahepatic disease. Patients should be referred to the transplant center before biopsy. In patients meeting UNOS criteria who are ineligible for transplant and in select patients with Child-Pugh class A or B liver function with tumors that are resectable, NCCN indicates resection is the preferred treatment option or locoregional therapy may be considered. Patients with unresectable HCC should be evaluated for liver transplantation and if the patient is a transplant candidate, then referral to a transplant center should be given or bridge therapy should be considered.
The NCCN guidelines on hepatobiliary cancers also indicate liver transplant is appropriate in select patients with extrahepatic cholangiocarcinoma, which is unresectable, but biliary and hepatic function is otherwise normal or when underlying chronic liver disease precludes surgery. These are level 2A recommendations based on lower-level evidence and uniform consensus.

The NCCN guidelines on neuroendocrine tumors V1.2015 indicate liver transplantation for neuroendocrine tumor liver metastases is considered investigational.\(^{184}\)

**Council of the British Transplant Society**

Liver transplantation guidelines for nonalcoholic steatohepatitis (NASH) were developed by the Council of the British Transplant Society and approved by the British Society of Gastroenterology, the British Association for the Study of Liver and NHS Blood and Transplant in 2012. These guidelines indicate liver transplantation may be considered for the treatment of NASH cirrhosis with end-stage liver disease or HCC.\(^{185}\) These guidelines are based primarily on consensus of expert opinion.

**American Association for the Study of Liver Diseases (AASLD) and the American Society of Transplantation**

AASLD and the AST issued a 2013 guideline for the long-term medical management of the pediatric patient after liver transplant.\(^{186}\) The guideline makes the following statement regarding liver transplant in children:

Pediatric liver transplant has dramatically changed the prognosis for many infants and children with liver failure and metabolic disease. As survival increases, long-term maintenance resources exceed perioperative care requirements. The most common indication for liver transplant in children is biliary atresia which accounts for 50% of all children requiring transplant in the U.S. and 74% in Europe.

**Lung and Lobar Lung Transplant**

**International Society for Heart and Lung Transplantation (IHS LT)**

In 2006 the Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation published guidelines for the selection of lung transplant candidates.\(^{178}\) See complete statement under Heart/Lung subheading above.
**Pancreas Transplant**

In 2014, the Board of Directors of the Organ Procurement and Transplantation Network issued an updated comprehensive list of transplant related policies.\(^{187}\)

Each candidate registered on the pancreas waiting list must meet one of the following requirements:

- Be diagnosed with diabetes
- Have pancreatic exocrine insufficiency
- Require the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons

The policy also delineated pancreas, kidney-pancreas, and islet allocation, classifications, and rankings.

**U.S. Preventive Services Task Force Recommendations**

The U.S. Preventive Services Task Force has not addressed solid organ transplantation.

**Medicare National Coverage**

**Heart Transplant**

Cardiac transplantation is covered under Medicare when performed in a facility that is approved by Medicare as meeting institutional coverage criteria. There are approximately 108 programs across the nation that meet these criteria.\(^{188}\)

The Centers for Medicare and Medicaid Services has stated that in certain limited cases, exceptions to the heart transplant criteria may be warranted if there is justification and if the facility ensures safety and efficacy objectives.
Heart/Lung Transplant

Heart/lung transplantation is covered under Medicare when performed in a facility that is approved by Medicare as meeting institutional coverage criteria. The Centers for Medicare and Medicaid Services has stated that under certain limited cases, exceptions to the criteria may be warranted if there is justification and if the facility ensures safety and efficacy objectives.

Kidney Transplant

The Medicare Benefit Policy Manual includes a chapter on end stage renal disease. In a section on identifying candidates for transplantation (140.1), it states, “After a patient is diagnosed as having ESRD, the physician should determine if the patient is suitable for transplantation. If the patient is a suitable transplant candidate, a live donor transplant is considered first because of the high success rate in comparison to a cadaveric transplant.”

Liver Transplant

Medicare covers adult liver transplantation for end-stage liver disease and HCC when performed in a facility that is approved by the Centers for Medicare and Medicaid Services (CMS) as meeting institutional coverage criteria for liver transplants. The following conditions must be met for coverage of HCC:

- The patient is not a candidate for subtotal liver resection;
- The patient's tumor(s) is less than or equal to 5 cm in diameter;
- There is no macrovascular involvement; and
- There is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone.

Beginning June 21, 2012, on review of this national coverage decision for new evidence, Medicare began offering coverage for adult liver transplantation, at Medicare administrative contractor discretion, for extrahepatic unresectable cholangiocarcinoma, liver metastases due to a neuroendocrine tumor and hemangioendothelioma. Adult liver transplantation is excluded for other malignancies.
Pediatric liver transplantation is covered for children (younger than age 18 years) when performed in a CMS-approved pediatric hospital for extrahepatic biliary atresia or any other form of end-stage liver disease, except that coverage is not provided for children with a malignancy extending beyond the margins of the liver or those with persistent viremia.

**Lung and Lobar Lung Transplant**

Lung transplantation is covered under Medicare when performed in a facility that is approved by Medicare as meeting institutional coverage criteria. The Centers for Medicare and Medicaid Services have stated that under certain limited cases, exceptions to the facility-related criteria may be warranted if there is justification and the facility ensures safety and efficacy objectives.

**Pancreas Transplant**

Allogeneic pancreas transplant is covered under Medicare when performed in a facility that is approved by Medicare as meeting institutional coverage criteria. The Centers for Medicare and Medicaid Services has made the following national coverage decision regarding pancreas transplant for Medicare recipients.

A. General – Pancreas transplantation is performed to induce an insulin-independent, euglycemic state in diabetic patients. The procedure is generally limited to those patients with severe secondary complications of diabetes, including kidney failure. However, pancreas transplantation is sometimes performed on patients with labile diabetes and hypoglycemic unawareness.

B. Nationally Covered Indications – Effective for services performed on or after July 1, 1999, whole organ pancreas transplantation is nationally covered by Medicare when performed simultaneous with or after a kidney transplant. If the pancreas transplant occurs after the kidney transplant, immunosuppressive therapy begins with the date of discharge from the inpatient stay for the pancreas transplant.

Effective for services performed on or after April 26, 2006, pancreas transplants alone (PA) are reasonable and necessary for Medicare beneficiaries in the following limited circumstances:

1. PA will be limited to those facilities that are Medicare-approved for kidney transplantation.
• Patients must have a diagnosis of type I diabetes

• Patient with diabetes must be beta cell autoantibody positive; or

2. Patient must demonstrate insulinopenia defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory’s measurement method. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose ≤225 mg/dL;

3. Patients must have a history of medically-uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization. Aforementioned complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;

4. Patients must have been optimally and intensively managed by an endocrinologist for at least 12 months with the most medically-recognized advanced insulin formulations and delivery systems;

5. Patients must have the emotional and mental capacity to understand the significant risks associated with surgery and to effectively manage the lifelong need for immunosuppression; and,

6. Patients must otherwise be a suitable candidate for transplantation.

C. Nationally Non-covered Indications – The following procedure is not considered reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act:

• Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial [see section 260.3.1 of the National Coverage Determinations Manual]).

References


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<th>Article</th>
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160. Gruessner AC. 2011 update on pancreas transplantation: Comprehensive trend analysis of 25,000 cases followed up over the course of twenty-four years at the International Pancreas Transplant Registry. Rev Diabet Stud. 2011;8(1):6-16. PMID 21720668


175. Farrington K, Covic A, Aucella F, et al. Clinical Practice Guideline on management of older patients with chronic kidney disease stage 3b or higher (eGFR <45 mL/min/1.73 m2). Nephrol Dial Transplant. Nov 2016;31(suppl 2):ii1-ii66. PMID 27807144


195. Blue Cross and Blue Shield Association. Medical Policy Reference Manual, Kidney Transplant policy No. 7.03.01, 2014; Pancreas Transplant policy No. 7.03.02, 2015; Liver Transplant policy No. 7.03.06, 2015; Lung and Lobar Lung Transplant policy No. 7.03.07, 2015; Heart/Lung Transplant policy No. 7.03.08, 2014; Heart Transplant policy No. 7.03.09, 2014.


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>07/01/02</td>
<td>Add to Surgery Section - New Policy. Replaces other transplant policies (PR.7.03.100, 102, 103, 104, 105, and 106)</td>
</tr>
<tr>
<td>05/13/03</td>
<td>Replace Policy - Scheduled review. References added and CPT code table updated.</td>
</tr>
<tr>
<td>01/01/04</td>
<td>Replace Policy - CPT code updates only.</td>
</tr>
<tr>
<td>05/11/04</td>
<td>Replace Policy - Policy reviewed by Nancy Aceto no changes needed at this time; new review date only. Appendices removed—no value.</td>
</tr>
<tr>
<td>09/01/04</td>
<td>Replace Policy - Policy renumbered from PR.7.03.109. No changes to dates.</td>
</tr>
<tr>
<td>05/10/05</td>
<td>Replace Policy - Scheduled review. References added. No change to policy statement.</td>
</tr>
<tr>
<td>02/06/06</td>
<td>Codes updated - No other changes.</td>
</tr>
<tr>
<td>05/09/06</td>
<td>Replace Policy - Scheduled review. References added; no change to policy statement.</td>
</tr>
<tr>
<td>05/26/06</td>
<td>Scope and Disclaimer Updates - No other changes.</td>
</tr>
<tr>
<td>02/26/07</td>
<td>Codes Updated - No other changes.</td>
</tr>
<tr>
<td>05/08/07</td>
<td>Replace Policy - Policy updated with literature review; reference added. No change in policy statement.</td>
</tr>
<tr>
<td>05/21/07</td>
<td>References Updated - Policy updated with information on Medicare coverage of heart transplants.</td>
</tr>
<tr>
<td>05/13/08</td>
<td>Replace Policy - Policy updated with literature search. Policy statement to include using a cadaver or living donor under kidney transplants as a medically necessary indication. Also to include “imminent end-stage liver failure” for patients under liver transplants as medically necessary.</td>
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<tr>
<td>03/10/09</td>
<td>Replace Policy - Policy updated with literature search; references added. No change to policy statement.</td>
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<td>02/09/10</td>
<td>Replace Policy - Policy updated with literature search. No change to policy statement.</td>
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<td>01/11/11</td>
<td>Replace Policy - Policy updated with literature search. No change to policy statement.</td>
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<td>01/06/12</td>
<td>Replace Policy – Policy updated with literature search; references added. No change to policy statement.</td>
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<tr>
<td>12/03/12</td>
<td>Update title to Related Policy 7.03.11.</td>
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<tr>
<td>01/29/13</td>
<td>Replace policy. Policy updated with literature search. No change to policy statement. References updated.</td>
</tr>
<tr>
<td>02/12/13</td>
<td>Update Related Policies, change title for 8.02.02.</td>
</tr>
<tr>
<td>05/30/13</td>
<td>Update Related Policies. Change title for 7.03.510.</td>
</tr>
<tr>
<td>02/10/14</td>
<td>Replace policy. Retransplant policy statements added to kidney, heart, heart/lung. Literature updated. References 35-39 added. ICD-9 Diagnosis codes were listed for informational purposes only and have been removed from the policy.</td>
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<td>Date</td>
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<tr>
<td>03/11/14</td>
<td>Coding Update. Codes 33.50, 33.51, 33.52, 33.6, 37.5, 50.4, 50.51, 50.59, 52.80, 52.81, 52.82, 52.83, and 55.69 were removed per ICD-10 mapping project; these codes are not utilized for adjudication of policy.</td>
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<td>03/31/15</td>
<td>Annual Review. Alphabetized names of organ transplants in policy statements. Related policy 7.03.05 added. Rationale section extensively reorganized by alphabetizing organ transplants and updated based on a literature review through December, 2014. References extensively renumbered and some references removed. Policy statements unchanged.</td>
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<td>08/19/15</td>
<td>Update Related Policies. Remove 7.03.510 and 8.02.02 then add 8.03.05 and 7.03.04.</td>
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<tr>
<td>09/24/15</td>
<td>Coding update. ICD-9 Procedure codes removed; these are informational only.</td>
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<tr>
<td>01/12/16</td>
<td>Annual Review. Policy updated with literature search; references added. No change to the policy statement.</td>
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<td>01/29/16</td>
<td>Coding update. Added HCPCS code S2152.</td>
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<tr>
<td>11/01/16</td>
<td>Update related policies. Removed 7.03.05 from related policies section as it was deleted (contents moved to 7.03.04).</td>
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<tr>
<td>01/01/17</td>
<td>Coding Update. Transplant benefit-related codes removed. Coding table moved to Policy Guidelines section. Updated titles of some Related Policies.</td>
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<tr>
<td>03/01/17</td>
<td>Annual Review, approved February 14, 2017. Policy updated with literature review through October 25, 2016; references renumbered. Policy statements unchanged.</td>
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<tr>
<td>04/14/17</td>
<td>Coding update; added HCPCS code S2060.</td>
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<tr>
<td>04/18/17</td>
<td>Coding update; added HCPCS code S2065.</td>
</tr>
<tr>
<td>09/01/17</td>
<td>Policy moved to new format. No changes to policy statement.</td>
</tr>
<tr>
<td>07/27/18</td>
<td>Coding update; added CPT 33935 to policy as it was inadvertently removed.</td>
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</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can also file a civil rights complaint with the U.S. Department of Health and Human Services.

Office for Civil Rights Complaint Portal, available at
http://www.hhs.gov/ocr/portal/lobby.jsf

This Notice has Important Information.

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):
لا يمكن للإعاقة أن تؤدي إلى الحصاد في مقابلة هؤلاء الذين يرغبون في تقديم خدماتهم.

Arabic (Arabic):
تقوم هذه الملاحظات بتفعيل حقوق المرضى الذين يرغبون في تقديم خدماتهم.

Arabic (Arabic):
لا يمكن للإعاقة أن تؤدي إلى الحصاد في مقابلة هؤلاء الذين يرغبون في تقديم خدماتهم.

Chinese (Chinese):
本通知有重要的信息。本通知可能有关于您透过 Premera Blue Cross 提交的申请或保险的重要信息。本通知可能有重要日期。您可能需要在截止日期之前采取行动，以保留您的健康保险或者费用补贴。如果您有疑问可以请您母语得到本信息和帮助。

En Español (Spanish):
Este aviso contiene información importante. Este aviso puede contener información importantes sobre su solicitud o cobertura a través de Premera Blue Cross. Podrían ser necesarios ciertos plazos. Usted debe solicitar esta información y ayuda en su idioma.

Français (French):

Deutsche (German):

Hmoob (Hmong):
Tsaab taddy xaj hov no maaj cov ntsiab lus tseem ceeb. Taaj zumm tsaab taddy xaj hov no maaj cov ntsiab lus tseem ceeb bseug kou dawv nok. Ntsiab tseem ceex haaw daim tawv tho koy pab lus yoo cov kho jowv seeg kou dawv nok maaj cov ntsiab lus tseem ceex haaw daim tawv tho koy pab lus yoo cov kho jowv seeg kou dawv nok maaj cov ntsiab lus tseem ceex haaw daim tawv tho koy pab lus yoo cov kho jowv seeg.

Ilokano (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalini nga adda ket naglaon iti napateg nga impormasion maipanggip iti aplikasyonyo nenow coverage babaen iti Premera Blue Cross. Daytoy ket mabalini dagiti importante a pelsa iti daytoy a pakdaar. Mabalini nga adda rumbeng nga aramidenyo nga adda sakbay dagiti partikular a naltingxd nga adda aldw tapno mapagtalaindeyo ti coverage ti salnu-atyo nenow tungon kadagiti gastos. Adda kargbenganyo a mangala iti daytoy nga impormasion ken tungon iti bukodyo a pagasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):