MEDICAL POLICY – 7.03.509
Solid Organ Transplants

BCBSA Ref. Policies: 7.03.01, 7.03.02, 7.03.06, 7.03.07 7.03.08 & 7.03.09

Effective Date: Nov. 1, 2018
Last Revised: Oct. 26, 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 Total Artificial Hearts and Implantable Ventricular Assist Devices
7.03.511 Intestinal and Multivisceral Organ Transplant Surgery
8.03.05 Outpatient Pulmonary Rehabilitation

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

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.
<table>
<thead>
<tr>
<th>Transplant</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart transplant</td>
<td>A human heart transplant may be considered medically necessary for adults or children with end-stage heart failure. “End stage heart failure” commonly reflects New York Heart Association functional class III or IV. (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.)</td>
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<td></td>
<td>Heart retransplantation after a failed primary heart transplant may be considered medically necessary in patients who meet criteria for heart transplantation.</td>
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<td><strong>Note:</strong> For additional information, see Additional Information</td>
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</table>
| Heart/lung transplant       | A combined heart/Lung transplant may be considered medically necessary for patients with end-stage cardiac and end-stage pulmonary disease including, but not limited to one of the following diagnoses:  
  - Chronic obstructive pulmonary disease with heart failure;  
  - Cystic fibrosis with severe heart failure;  
  - Eisenmenger complex with irreversible pulmonary hypertension and heart failure;  
  - Emphysema with severe heart failure;  
  - Irreversible primary pulmonary hypertension with heart failure;  
  - Nonspecific severe pulmonary fibrosis, with severe heart failure;  
  - Pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure  
Heart/lung retransplantation after a failed primary heart/lung transplant may be considered medically necessary for patients who meet criteria for heart/lung transplantation.                                                                                                                                                                                                                                                                                                                                 |
<p>|                             | <strong>Note:</strong> For additional information, see Additional Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |</p>
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<thead>
<tr>
<th>Transplant</th>
<th>Medical Necessity</th>
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<tbody>
<tr>
<td>Kidney transplant</td>
<td>Kidney transplants with either a living or a deceased (cadaver) donor may be considered medically necessary for patients with documented end-stage renal disease.</td>
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<td></td>
<td>Kidney retransplant after a failed primary kidney transplant may be considered medically necessary in patients who meet criteria for kidney transplantation.</td>
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<td><strong>Note:</strong> For additional information, see Additional Information</td>
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<tr>
<td>Liver transplant</td>
<td>Liver transplants, using a deceased (cadaver) or living donor, may be considered medically necessary for patients with end-stage liver failure due to irreversibly damaged livers. Etiologies of end-stage liver disease include, but are not limited to, the following:</td>
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<tr>
<td></td>
<td>- Cholestatic liver diseases</td>
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<td></td>
<td>- Familial amyloid polyneuropathy</td>
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<td></td>
<td>- Hepatocellular diseases</td>
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<td>- Inborn errors of metabolism</td>
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<td></td>
<td>- Primary hepatocellular carcinoma</td>
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<td></td>
<td>- Trauma and toxic reactions</td>
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<tr>
<td></td>
<td>- Vascular disease</td>
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<tr>
<td></td>
<td>Liver transplantation may be considered medically necessary in patients with polycystic disease of the liver who have massive hepatomegaly causing obstruction or functional impairment.</td>
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<tr>
<td></td>
<td>Liver transplantation may be considered medically necessary in patients with unresectable hilar cholangiocarcinoma.</td>
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<tr>
<td></td>
<td>Liver transplantation may be considered medically necessary in pediatric patients with nonmetastatic hepatoblastoma.</td>
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<tr>
<td></td>
<td>Liver retransplantation may be considered medically necessary in patients with:</td>
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<tr>
<td></td>
<td>- Chronic rejection</td>
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<tr>
<td></td>
<td>- Hepatic artery thrombosis</td>
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<tr>
<td>Transplant</td>
<td>Medical Necessity</td>
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<td>------------------------------------</td>
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<tr>
<td></td>
<td>• Ischemic type biliary lesions after donation after cardiac death</td>
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<tr>
<td></td>
<td>• Primary graft nonfunction</td>
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<tr>
<td></td>
<td>• Recurrent non-neoplastic disease causing late graft failure.</td>
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<tr>
<td>Liver transplantation is considered not medically necessary in the following patients:</td>
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<tr>
<td></td>
<td>• Patients with hepatocellular carcinoma that has extended beyond the liver</td>
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<td></td>
<td>• Patients with ongoing alcohol and/or drug abuse. (Evidence for abstinence may vary among liver transplant programs, but generally a minimum of 3 months is required.)</td>
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<tr>
<td>Liver transplantation is investigational in the following situations:</td>
<td></td>
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<tr>
<td></td>
<td>• Patients with intrahepatic cholangiocarcinoma</td>
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<tr>
<td></td>
<td>• Patients with neuroendocrine tumors metastatic to the liver</td>
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<tr>
<td><strong>Note:</strong> For additional information, see Additional Information</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Liver/kidney transplant</th>
<th>Combined liver-kidney transplantation may be considered medically necessary in patients who qualify for liver transplantation and have advanced irreversible kidney disease.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung transplant and lobar lung transplant</td>
<td>Lung transplants may be considered medically necessary for patients with irreversible, progressively disabling, end-stage pulmonary disease unresponsive to maximum medical therapy.</td>
</tr>
<tr>
<td></td>
<td>A lobar lung transplant from a living or deceased donor may be considered medically necessary for patients with end-stage pulmonary disease.</td>
</tr>
<tr>
<td></td>
<td>Lung or lobar lung retransplantation after a failed lung or lobar lung transplant may be considered medically necessary in patients who meet criteria for lung transplantation.</td>
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<tr>
<td><strong>Note:</strong> For additional information, see Additional Information</td>
<td></td>
</tr>
<tr>
<td>Pancreas transplant</td>
<td>Pancreas transplant after a prior kidney transplant may be considered medically necessary in patients with insulin-</td>
</tr>
</tbody>
</table>

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 that persists despite optimal medical management.

Pancreas retransplant after a failed primary pancreas transplant may be considered medically necessary in patients who meet criteria for pancreas transplantation.

**Note:** For additional information, see Additional Information

<table>
<thead>
<tr>
<th>Transplant</th>
<th>Medical Necessity</th>
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<tbody>
<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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</table>

<table>
<thead>
<tr>
<th>Transplant</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid organ transplants (other)</td>
<td>Solid organ transplants other than those addressed above are considered investigational (see Related Policies).</td>
</tr>
</tbody>
</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>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>32851</td>
<td>Lung transplant, single; without cardiopulmonary bypass</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>32852</td>
<td>Lung transplant, single; with cardiopulmonary bypass</td>
</tr>
<tr>
<td>32853</td>
<td>Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass</td>
</tr>
<tr>
<td>32854</td>
<td>Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass</td>
</tr>
<tr>
<td>33935</td>
<td>Heart-lung transplant with recipient cardiectomy-pneumonectomy</td>
</tr>
<tr>
<td>33945</td>
<td>Heart transplant, with or without recipient cardiectomy</td>
</tr>
<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>
</tr>
<tr>
<td>47399</td>
<td>Unlisted procedure, liver</td>
</tr>
<tr>
<td>48554</td>
<td>Transplantation of pancreatic allograft</td>
</tr>
<tr>
<td>50360</td>
<td>Renal allotransplantation, implantation of graft; without recipient nephrectomy</td>
</tr>
<tr>
<td>50365</td>
<td>Renal allotransplantation, implantation of graft; with recipient nephrectomy</td>
</tr>
</tbody>
</table>

**HCPCS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>S2060</td>
<td>Lobar lung transplantation</td>
</tr>
<tr>
<td>S2065</td>
<td>Simultaneous pancreas kidney transplantation</td>
</tr>
<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>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

### Related Information

**New York Heart Association (NYHA) Classification**

| Class I | No symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc. |
**New York Heart Association (NYHA) Classification**

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class II</td>
<td>Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity</td>
</tr>
<tr>
<td>Class III</td>
<td>Marked limitation in activity due to symptoms, even during less-than-ordinary activity, eg, walking short distances (20–100 m). Comfortable only at rest.</td>
</tr>
<tr>
<td>Class IV</td>
<td>Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients</td>
</tr>
</tbody>
</table>

**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.

Transplants should be considered for coverage under the transplant benefit and should be evaluated for charge in accordance with traditional transplant benefits.

Which expenses are incurred during the evaluation and procurement of organs and tissues should be compared with the scope of human organ transplant benefits for coverage determination. Typically, the following are considered human organ transplant benefits:

- hospitalization of the recipient for medically recognized transplants from a donor to a transplant recipient;
- prehospital workup and hospitalization of a living donor undergoing a partial hepatectomy should be considered as part of the recipient transplant costs;
- evaluation tests requiring hospitalization to determine the suitability of both potential and actual donors, when such tests cannot be safely and effectively performed on an outpatient basis;
- hospital room, board, and general nursing in semiprivate rooms;
- special care units, such as coronary and intensive care;
- hospital ancillary services;
- physicians’ services for surgery, technical assistance, administration of anesthetics, and medical care;
- acquisition, preparation, transportation, and storage of organ;
- diagnostic services;
• drugs that require a prescription by federal law.

Other examples of benefits include: specific charges for participation with registries for organ procurement, operating rooms, supplies, use of hospital equipment, and transportation of the tissue or organ to be evaluated.

Administration of products with a specific transplant benefit needs to be defined as to:

• when the benefit begins (at the time of admission for the transplant or once the patient is determined eligible for a transplant, which may include tests or office visits before transplant);

• when the benefit ends (at the time of discharge from the hospital or at the end of required follow-up, including the immunosuppressive drugs administered on an outpatient basis).

Coverage usually is not provided for:

• human organ transplant services, for which the cost is covered or funded by governmental, foundational, or charitable grants;

• organs sold rather than donated to the recipient;

• an artificial organ.

Additional Information

Heart Transplant

Adult Patients

Accepted Indications for Cardiac 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

**Heart/Lung Transplant**

When the candidate is eligible to receive a heart in accordance with United Network for Organ Sharing (UNOS) guidelines for cardiac transplantation, the lung(s) shall be allocated to the heart/lung candidate from the same donor. When the candidate is eligible to receive a lung in accordance with the UNOS Lung Allocation System, the heart shall be allocated to the heart/lung candidate from the same donor “if no suitable Status 1A isolated heart candidates are eligible to receive the heart” (Organ Procurement and Transplantation Network [2018]).

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 highest priority.

The following factors are considered in assessing the severity of cardiac illness: reliance on continuous mechanical ventilation, infusion of intravenous inotropes, and/or dependency on mechanical circulatory support (ie, total artificial heart, intra-aortic balloon pump, extracorporeal membrane oxygenator, ventricular assist device). Factors considered in assessing the severity of pulmonary illness include increased pulmonary artery systolic pressure (>60 mm Hg), pulmonary arterial hypertension, and/or elevated pulmonary vascular resistance.
Additional criteria may be considered in pediatric patients, including diagnosis of a 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.

In both adult and pediatric patients, isolated cardiac or pulmonary transplantations are preferred to combined heart/lung transplantation when medical or surgical management—other than organ transplantation—is available.

Full OPTN guidelines are available online (at https://optn.transplant.hrsa.gov/governance/policies/ Accessed October 2018)

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

**Renal Transplant**

Indications for renal transplant include a creatinine level of greater than 8 mg/dL, or greater than 6 mg/dL in symptomatic diabetic patients; however, consideration for listing for renal transplant may start well before the creatinine level reaches this point, based on the anticipated time that a patient may spend on the waiting list.

**Liver Transplant**

Etiologies of end-stage liver disease:

A. *Hepatocellular diseases*
   - Alcoholic liver disease
   - Viral hepatitis (either A, B, C, or non-A, non-B)
   - Autoimmune hepatitis
   - $\alpha_1$-Antitrypsin deficiency
   - Hemochromatosis
   - Nonalcoholic steatohepatitis
o Protoporphyria
o Wilson disease.

**B. Cholestatic liver diseases**
- Primary biliary cirrhosis
- Primary sclerosing cholangitis with development of secondary biliary cirrhosis
- Biliary atresia.

**C. Vascular disease**
- Budd-Chiari syndrome.

**D. Primary hepatocellular carcinoma**

**E. Inborn errors of metabolism**

**F. Trauma and toxic reactions**

**G. Miscellaneous**
- Familial amyloid polyneuropathy

*The Model for End-stage Liver Disease (MELD) and Pediatric End-stage Liver Disease (PELD) scores range from 6 (less ill) to 40 (gravely ill). The MELD and PELD scores will change during a patient’s tenure on the waiting list.*

Patients with liver disease related to alcohol or drug abuse must be actively involved in a substance abuse treatment program.

Tobacco consumption is a contraindication.

Patients with polycystic disease of the liver do not develop liver failure but may require transplantation due to the anatomic complications of a hugely enlarged liver. The MELD and PELD score may not apply to these cases. One of the following complications should be present:

- Enlargement of liver impinging on respiratory function
- Extremely painful enlargement of liver
- Enlargement of liver significantly compressing and interfering with function of other abdominal organs.
Patients with familial amyloid polyneuropathy do not experience liver disease per se, but develop polyneuropathy and cardiac amyloidosis due to the production of a variant transthyretin molecule by the liver. MELD and PELD exception criteria and scores may apply to these cases. Candidacy for liver transplant is an individual consideration based on the morbidity of the polyneuropathy. Many patients may not be candidates for liver transplant alone due to coexisting cardiac disease.

**Hepatocellular Carcinoma**

Criteria used for patient selection of hepatocellular carcinoma (HCC) patients eligible for liver transplant include the Milan criteria, which is considered the criterion standard, the University of California, San Francisco expanded criteria, and United Network of Organ Sharing (UNOS) criteria.

**Milan Criteria**

A single tumor 5 cm or less or 2 to 3 tumors 3 cm or less.

**University of California, San Francisco Expanded Criteria**

A single tumor 6.5 cm or less or up to 3 tumors 4.5 cm or less, and a total tumor size of 8 cm or less.

**UNOS Stage T2 Criteria**

A single tumor 2 cm or greater and up to 5 cm or less or 2 to 3 tumors 1 cm or greater and up to 3 cm or less and without extrahepatic spread or macrovascular invasion. UNOS criteria were updated in 2018 ([https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf) Accessed October 2018)

Patients with HCC are appropriate candidates for liver transplant only if the disease remains confined to the liver. Therefore, the patient should be periodically monitored while on the waiting list, and if metastatic disease develops, the patient should be removed from the transplant waiting list. Also, at the time of transplant, a backup candidate should be scheduled. If locally extensive or metastatic cancer is discovered at the time of exploration before
hepatectomy, the transplant should be aborted, and the backup candidate scheduled for transplant.

Note that liver transplantation for those with T3 HCC is not prohibited by UNOS guidelines, but such patients do not receive any priority on the waiting list. All patients with HCC awaiting transplantation are reassessed at 3-month intervals. Those whose tumors have progressed and are no longer stage T2 will lose the additional allocation points.

Additionally, nodules identified through imaging of cirrhotic livers are given a class 5 designation. Class 5B and 5T nodules are eligible for automatic priority. Class 5B criteria consist of a single nodule 2 cm or larger and up to 5 cm (T2 stage) that meets specified imaging criteria. Class 5T nodules have undergone subsequent locoregional treatment after being automatically approved on initial application or extension. A single class 5A nodule (>1 cm and <2 cm) corresponds to T1 HCC and does not qualify for automatic priority. However, combinations of class 5A nodules are eligible for automatic priority if they meet stage T2 criteria. Class 5X lesions are outside of stage T2 and ineligible for automatic exception points. Nodules less than 1 cm are considered indeterminate and are not considered for additional priority. Therefore, the UNOS allocation system provides strong incentives to use locoregional therapies to downsize tumors to T2 status and to prevent progression while on the waiting list.

**Cholangiocarcinoma**

According to the Organ Procurement and Transplantation Network (OPTN) policy on liver allocation, candidates with cholangiocarcinoma meeting the following criteria will be eligible for a MELD or PELD exception with a 10% mortality equivalent increase every 3 months:

- Centers must submit a written protocol for patient care to the OPTN and UNOS Liver and Intestinal Organ Transplantation Committee before requesting a MELD score exception for a candidate with cholangiocarcinoma. This protocol should include selection criteria, administration of neoadjuvant therapy before transplantation, and operative staging to exclude patients with regional hepatic lymph node metastases, intrahepatic metastases, and/or extrahepatic disease. The protocol should include data collection as deemed necessary by the OPTN and UNOS Liver and Intestinal Organ Transplantation Committee.

- Candidates must satisfy diagnostic criteria for hilar cholangiocarcinoma: malignant-appearing stricture on cholangiography and one of the following: carbohydrate antigen 19-9 100 U/mL, or and biopsy or cytology results demonstrating malignancy, or aneuploidy. The tumor should be considered unresectable on the basis of technical considerations or underlying liver disease (eg, primary sclerosing cholangitis).
• If cross-sectional imaging studies (computed tomography scan, ultrasound, magnetic resonance imaging) demonstrate a mass, the mass should be 3 cm or less.

• Intra- and extrahepatic metastases should be excluded by cross-sectional imaging studies of the chest and abdomen at the time of initial exception and every 3 months before score increases.

• Regional hepatic lymph node involvement and peritoneal metastases should be assessed by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neoadjuvant therapy is initiated.

• Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative, or percutaneous approaches) should be avoided because of the high risk of tumor seeding associated with these procedures.

**Living Donor Criteria**

Donor morbidity and mortality are prime concerns in donors undergoing right lobe, left lobe, or left lateral segment donor partial hepatectomy as part of living donor liver transplantation. Partial hepatectomy is a technically demanding surgery, the success of which may be related to the availability of an experienced surgical team. The American Society of Transplant Surgeons proposed the following guidelines for living donors (American Society of Transplant Surgeons: Ethics Committee. American Society of Transplant Surgeons' position paper on adult-to-adult living donor liver transplantation. Liver Transplant. 2000;6(6):815-817. PMID 11084076):

• They should be healthy individuals who are carefully evaluated and approved by a multidisciplinary team including hepatologists and surgeons to assure that they can tolerate the procedure

• They should undergo evaluation to ensure that they fully understand the procedure and associated risks

• They should be of legal age and have sufficient intellectual ability to understand the procedures and give informed consent

• They should be emotionally related to the recipients

• They must be excluded if the donor is felt or known to be coerced

• They need to have the ability and willingness to comply with long-term follow-up.
**Lung Transplant**

Bilateral lung transplantation is typically required when chronic lung infection and disease is present (ie, associated with cystic fibrosis and bronchiectasis). Some, but not all, cases of pulmonary hypertension will require bilateral lung transplantation.

Bronchiolitis obliterans is associated with chronic lung transplant rejection, and thus may be the etiology of a request for lung retransplantation.

In 2010, a simple priority system was implemented for children younger than age 12 years. Under this system, children younger than 12 years with respiratory lung failure and/or pulmonary hypertension who meet criteria are considered “priority 1” and all other candidates in the age group are considered “priority 2”. A lung review board has the authority to adjust scores on appeal for adults and children.

**Pancreas Transplant**

Candidates for pancreas transplant alone should also meet one of the following severity of illness criteria:

- Documented severe hypoglycemia unawareness as evidenced by chart notes or emergency department visits or

- Documented potentially life-threatening labile diabetes, as evidenced by chart notes or hospitalization for diabetic ketoacidosis.

Additionally, most pancreas transplant patients will have type 1 diabetes. Those transplant candidates with type 2 diabetes, in addition to being insulin-dependent, should also not be obese (body mass index should be ≤32 kg/m2). According to International Pancreas Transplant Registry data, in 2010, 7% of pancreas transplant recipients had type 2 diabetes (Gruessner [2011]).

Although there are no standard guidelines for multiple pancreas transplants, the following information may aid in case review:

- If there is early graft loss resulting from technical factors (eg, venous thrombosis), a retransplant may generally be performed without substantial additional risk.
• Long-term graft losses may result from chronic rejection, which is associated with increased risk of infection following long-term immunosuppression, and sensitization, which increases the difficulty of finding a negative cross-match. Some transplant centers may wait to allow reconstitution of the immune system before initiating retransplant with an augmented immunosuppression protocol.

Contraindications

Potential contraindications for solid organ transplant are subject to the judgment of the transplant center and 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 disease not attributed to liver 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.

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

For individuals who have end-stage heart failure who receive a heart transplant, the evidence includes case series and registry data. Relevant outcomes include overall survival, 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 in patients for whom the procedure is expected to be futile due to comorbid disease or for 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 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 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.

Heart/Lung Transplant

For individuals who have end-stage cardiac and pulmonary disease who receive combined heart/lung transplant, the evidence includes case series and registry data. Relevant outcomes include overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. The available literature reports on 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. Transplant may be the only option for some patients with end-stage cardiopulmonary disease. Heart/lung transplant is contraindicated for patients in 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 a combined heart/lung transplant complicated by graft failure or severe dysfunction of the heart/lung and who receive a combined heart/lung retransplant, the evidence includes case series and registry data. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. A very limited amount of data has suggested that, after controlling for confounding variables, survival rates after primary and repeat heart/lung transplants are similar. Findings are inconclusive due to the small number of cases of repeat heart/lung transplants reported in the published literature. Repeat heart/lung transplantation is, however, likely to improve outcomes in patients with a prior failed transplant who meet the clinical criteria for heart/lung transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Kidney Transplant**

For individuals who have end-stage renal disease 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 reasonably high survival rates 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 reasonably high survival rates after kidney retransplant (eg, 5-year patient survival rates ranging from 87% to 96%) for appropriately selected patients. 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**

For individuals who have hepatocellular disease who receive a liver transplant, the evidence includes case series, registry studies, and systematic reviews. Relevant outcomes include overall survival, morbid events, and treatment-related morbidity and mortality. Studies on liver transplantation for viral hepatitis have found that survival is lower than for other liver diseases. Although these statistics raise questions about the most appropriate use of a scarce resource (donor livers), the long-term survival rates are significant in a group of patients who have no other treatment options. Also, survival can be improved by the eradication of the hepatitis virus before transplantation. For patients with nonalcoholic steatohepatitis (NASH), overall survival rates have been shown to be similar to other indications for liver transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary hepatocellular carcinoma (HCC) who receive a liver transplant, the evidence includes systematic reviews of observational studies. Relevant outcomes include overall survival, morbid events, and treatment-related morbidity and mortality. In the past, long-term outcomes in patients with primary hepatocellular malignancies had been poor (19%) compared with the overall survival of liver transplant recipients. However, the recent use of standardized patient selection criteria (eg, the Milan criteria diameter) has dramatically improved overall survival rates. In appropriately selected patients, a liver transplant has been shown to result in higher survival rates than resection. In patients who present with unresectable organ-confined disease, transplant represents the only curative approach. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have extrahepatic cholangiocarcinoma who receive a liver transplant, the evidence includes systematic reviews of observational studies. Relevant outcomes include overall survival, morbid events, and treatment-related morbidity and mortality. For patients with extrahepatic (hilar or perihilar) cholangiocarcinoma who are treated with adjuvant chemotherapy, survival rates have been reported as high as 76%. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have intrahepatic cholangiocarcinoma who receive a liver transplant, the evidence includes registry studies. Relevant outcomes include overall survival, morbid events,
and treatment-related morbidity and mortality. Five-year survival rates after liver transplantation in patients with cholangiocarcinoma are less than 30%. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have neuroendocrine tumors (NETs) who receive a liver transplant, the evidence includes systematic reviews of case series. Relevant outcomes include overall survival, morbid events, and treatment-related morbidity and mortality. In select patients with nonresectable, hormonally active liver metastases refractory to medical therapy, liver transplantation has been considered as an option to extend survival and minimize endocrine symptoms. While some centers may perform liver transplants on select patients with neuroendocrine tumors, the available studies are limited by their heterogeneous populations. Further studies are needed to determine the appropriate selection criteria. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pediatric hepatoblastoma who receive a liver transplant, the evidence includes case series. Relevant outcomes include overall survival, morbid events, and treatment-related morbidity and mortality. 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 among the United Network for Organ Sharing criteria for patients eligible for liver transplantation. 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 liver transplant who receive a liver retransplant, the evidence includes observational studies. Relevant outcomes include overall survival, morbid events, and treatment-related morbidity and mortality. 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 has suggested outcomes after retransplantation may be less favorable than for initial transplantation in some patients, long-term survival benefits have been demonstrated. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with indications for liver and kidney transplant who receive a combined liver-kidney transplant (CLKT), the evidence includes registry studies. Relevant outcomes include overall survival, morbid events, and treatment-related morbidity and mortality. Most of the evidence involves adults with cirrhosis and kidney failure. Indications for CLKT in children are rare and often congenital and include liver-based metabolic abnormalities affecting the kidney, along with structural diseases affecting both the liver and kidney. In both adults and children, comparisons with either liver or kidney transplantation alone would suggest that CLKT is no
worse, and possibly better, for graft and patient survival. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Lung and Lobar Lung Transplantation**

For individuals who have end-stage pulmonary disease who receive a lung transplant, the evidence includes case series and registry studies. Relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. International registry data on a large number of patients receiving lung transplantation (>50,000) found relatively high patient survival rates, especially among those who survived the first year posttransplant. After adjusting for potential confounding factors, survival did not differ significantly after single- or double-lung transplant. Lung transplantation may be the only option for some patients with end-stage lung disease. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end-stage pulmonary disease who receive a lobar lung transplant, the evidence includes case series and systematic reviews. Relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. There are less data on lung lobar transplants than on whole-lung transplants, but several case series have reported reasonably similar survival outcomes between the procedures, and lung lobar transplants may be the only option for patients unable to wait for a whole-lung transplant. A 2017 systematic review found 1-year survival rates in available published studies ranging from 50% to 100%. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a prior lung or lobar transplant who meet criteria for a lung transplant who receive a lung or lobar lung retransplant, the evidence includes case series and registry studies. Relevant outcomes are overall survival, change in disease status, treatment-related mortality and morbidity. Data from registries and case series have found favorable outcomes with lung retransplantation in patients who meet criteria for initial lung transplantation. Given the exceedingly poor survival prognosis without retransplantation of patients who have exhausted other treatments, the evidence of a moderate level of posttransplant survival may be considered sufficient in this patient population. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
Pancreas Transplant

For individuals who have insulin-dependent diabetes who receive a pancreas transplant after a kidney transplant, the evidence includes case series and registry studies. Relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. Data from national and international registries have found relatively high patient survival rates with a pancreas transplant after a kidney transplant (eg, a 3-year survival rate of 93%). A 2012 analysis of data from a single center found similar patient survival and death-censored pancreas graft survival rates with a pancreas transplant after a kidney transplant or a simultaneous pancreas and kidney (SPK) transplant. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have insulin-dependent diabetes with uremia who receive SPK transplants, the evidence includes registry studies. Relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. Data from national and international registries have found relatively high patient survival rates after SPK transplant. A retrospective analysis found a higher survival rate in patients with type 1 diabetes who had an SPK transplant vs those on a waiting list. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have insulin-dependent diabetes and severe complications who receive pancreas transplant alone, the evidence includes registry studies. Relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. Data from international and national registries have found that graft and patient survival rates after pancreas transplant alone have improved over time (eg, 3-year survival of 95%). 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 pancreas transplant who still meet criteria for a pancreas transplant who receive pancreas retransplantation, the evidence includes case series and registry studies. Relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. National data and specific transplant center data have generally found similar graft and patient survival rates after pancreas retransplantation compared with initial transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
# Ongoing and Unpublished Clinical Trials

## Clinical Trials for Kidney Transplant

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NCT: national clinical trial.

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NCT: national clinical trial.

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NCT: national clinical trial.
Clinical Trials for Pancreas Transplant

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NCT: national clinical trial.

Practice Guidelines and Position Statements

Heart Transplant

American College of Cardiology Foundation and American Heart Association

Guidelines from the American College of Cardiology Foundation and 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.

International Society for Heart and Lung Transplantation

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>
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<th>Recommendation</th>
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<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>
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**Recommendation** | **LOE**
---|---
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 | C

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.

The 2010 guidelines from 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.”

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 E\textsubscript{1} 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/m\textsuperscript{2} 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/m\textsuperscript{2} 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 multiorgan 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.

Heart/Lung Transplant

International Society for Heart and Lung Transplantation

The International Society for Heart and Lung Transplantation (2014) updated its consensus-based guidelines on the selection of lung transplant recipients. These guidelines made the following statements about lung transplantation:

“Lung transplantation should be considered for adults with chronic, end-stage lung disease who meet all the following general criteria:

- High (>50%) risk of death from lung disease within 2 years if lung transplantation is not performed.
- High (>80%) likelihood of surviving at least 90 days after lung transplantation.
- High (>80%) likelihood of 5-year post-transplant survival from a general medical perspective provided that there is adequate graft function.”

For combined heart/lung transplant, the guidelines have stated that patients with irreversible myocardial dysfunction or irreparable congenital defects in conjunction with intrinsic lung disease or severe pulmonary arterial hypertension are appropriate candidates for heart/lung transplantation. The guidelines also mentioned that isolated bilateral lung transplantation is associated with comparable or better outcomes in most patients with pulmonary hypertension associated with right ventricular failure.

Kidney Transplant

American Society of Transplant Surgeons et al

The American Society of Transplant Surgeons, the American Society of Transplantation, the Association of Organ Procurement Organizations, and the United Network for Organ Sharing (2011) issued a joint position statement recommending modifications to the National Organ Transplant Act of 1984. The joint recommendation stated that the potential pool of organs
from HIV-infected donors should 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 Act permitted the use of this group of organ donors.

**Liver Transplant**

**International Consensus Conference**

The Milan criteria were recommended for use as the benchmark for patient selection, although it was suggested that the Milan criteria might be modestly expanded based on data from expansion studies that demonstrated outcomes are comparable with 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.

Regarding liver retransplantation, the consensus criteria issued a weak recommendation for retransplantation after graft failure of a living donor transplant for hepatocellular carcinoma (HCC) in patients meeting regional criteria for a deceased donor liver transplant. A strong recommendation was issued against liver retransplantation with a deceased donor for graft failure for patients exceeding regional criteria. Also, the consensus criteria issued a strong recommendation that liver retransplantation for recurrent HCC would not be appropriate. However, a de novo case of HCC may be treated as a new tumor, and retransplantation may be considered even though data to support this is limited.

**American Association for the Study of Liver Diseases et al**

The American Association for the Study of Liver Diseases and the American Society of Transplantation (2013) issued joint guidelines on evaluating patients for liver transplant. These guidelines indicated liver transplantation for severe acute or advanced chronic liver disease after all effective medical treatments have been attempted. The formal evaluation should confirm the irreversible nature of the liver disease and lack of effective alternative medical therapy.

The guidelines also stated that liver transplant is indicated for the following conditions:

- Acute liver failure complications of cirrhosis
- Liver-based metabolic condition with systemic manifestations
  - α1-Antitrypsin deficiency
  - Familial amyloidosis
  - Glycogen storage disease
  - Hemochromatosis
  - Primary oxaluria
  - Wilson disease
- Systemic complications of chronic liver disease.

The guidelines also included 1-A recommendations (strong recommendation with high-quality evidence) for a liver transplant that:

- “Tobacco consumption should be prohibited in LT [liver transplant] candidates.”
- “Patients with HIV infection are candidates for LT if immune function is adequate and the virus is expected to be undetectable by the time of LT.”
- “LT candidates with HCV [hepatitis C virus] have the same indications for LT as for other etiologies of cirrhosis.”

Contraindications to liver transplant included:

- “MELD [Model for End-stage Liver Disease] score < 15
- Severe cardiac or pulmonary disease
- AIDS
- Ongoing alcohol or illicit substance abuse
- Hepatocellular carcinoma with metastatic spread
- Uncontrolled sepsis
- Anatomic abnormality that precludes liver transplantation
- Intrahepatic cholangiocarcinoma
- Extrahepatic malignancy
- Fulminant hepatic failure
- Hemangiosarcoma
- Persistent noncompliance
- Lack of adequate social support system"

The American Association for the Study of Liver Diseases, the American Society of Transplantation, and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition issued joint guidelines on the evaluation of the pediatric patients for liver transplant in 2014. The guidelines stated that “disease categories suitable for referral to a pediatric LT program are similar to adults: acute liver failure, autoimmune, cholestasis, metabolic or genetic, oncologic, vascular, and infectious. However, specific etiologies and outcomes differ widely from adult patients, justifying independent pediatric guidelines.” The indications listed for liver transplantation included biliary atresia, Alagille syndrome, pediatric acute liver failure, hepatic tumors, HCC, hemangioendothelioma, cystic fibrosis-associated liver disease, urea cycle disorders, immune-mediated liver disease, along with other metabolic or genetic disorders.

**National Comprehensive Cancer Network (NCCN)**

The National Comprehensive Cancer Network (NCCN) guidelines on hepatobiliary cancers (v2.2018) recommend referral to a liver transplant center or bridge therapy for patients with HCC meeting United Network of Organ Sharing criteria of a single tumor 2 to 5 cm, or 2 to 3 tumors 3 cm or less with no macrovascular involvement or extrahepatic disease. In patients 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; 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 that 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 (v.2.208) indicate liver transplantation for neuroendocrine tumor liver metastases is considered investigational despite “encouraging” 5-year survival rates.
Council of the British Transplant Society et al

Liver transplantation guidelines for nonalcoholic steatohepatitis 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 the National Health Service Blood and Transplant in 2012. These guidelines indicated liver transplantation might be considered for the treatment of nonalcoholic steatohepatitis cirrhosis with end-stage liver disease or HCC. These guidelines are based primarily on consensus of expert opinion.

Lung and Lobar Lung Transplant

International Society for Heart and Lung Transplantation

Initial Transplant

The International Society for Heart and Lung Transplantation (2006) published consensus-based guidelines on selection of lung transplant candidates. The guidelines stated that:

“Lung transplantation is now a generally accepted therapy for the management of a wide range of severe lung disorders, with evidence supporting quality of life and survival benefit for lung transplant recipients. However, the number of donor organs available remains far fewer than the number of patients with end-stage lung disease who might potentially benefit from the procedure. It is of primary importance, therefore, to optimize the use of this resource, such that the selection of patients who receive a transplant represents those with realistic prospects of favorable long-term outcomes....”

In 2014, these recommendations were updated for pulmonary vascular disease. The Society recommended including a transplant list for patients with New York Heart Association class III or IV disease, despite 3 months or more of combination therapy. Additional clinical indications included a cardiac index of less than 2 L/min/m², a mean right atrial pressure of greater than 15 mm Hg, and a 6-minute walk distance of fewer than 350 meters. Also, recommended for transplant listing were significant hemoptysis, pericardial effusion, or signs of progressive right heart failure. Other common indications for lung transplant include interstitial lung disease, idiopathic pulmonary fibrosis, cystic fibrosis, and chronic obstructive pulmonary disease.
Retransplant

Lung retransplantation was addressed briefly, with the consensus statement noting that “criteria for candidate selection for lung retransplantation generally mirror the criteria used for selection for initial lung transplantation.”

American Thoracic Society et al

Evidence-based recommendations from the American Thoracic Society and 3 international cardiac societies were published in 2011. For appropriately selected patients with idiopathic pulmonary fibrosis, the group et al recommended lung transplantation (strong recommendation, low-quality evidence).

Pancreas Transplant

The Organ Procurement and Transplantation Network updated its comprehensive list of transplant related policies, most recently in June 2018.

For pancreas registration: “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”

For combined kidney plus pancreas registration: “Each candidate registered on the kidney-pancreas waiting list must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency.”

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. 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 facility ensures safety and efficacy objectives.

**Heart/Lung Transplant**

Heart/lung transplantation is covered under Medicare when performed in a facility approved by Medicare as meeting institutional coverage criteria. 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 facility ensures safety and efficacy objectives.

**Kidney Transplant**

The Medicare Benefit Policy Manual includes a chapter on end-stage renal disease. A section on identifying candidates for transplantation (140.1) states:

After a patient is diagnosed as having ESRD [end-stage renal disease], 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. Whether one or multiple potential donors are available, the following sections provide a general description of the usual course of events in preparation for a live-donor 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 & Medicaid Services 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; and

• The transplant is furnished in a facility that is approved by CMS [Centers for Medicare & Medicaid Services]....

Beginning in June 2012, on review of this national coverage decision for new evidence, Medicare began covering 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 (< 18 years of age) when performed at pediatric hospitals approved by the Centers for Medicare & Medicaid Services. Coverage includes extrahepatic biliary atresia or any other form of end-stage liver disease, except 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 approved by Medicare as meeting institutional coverage criteria. The Centers for Medicare & 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**

An allogeneic pancreas transplant is covered under Medicare when performed in a facility approved by Medicare as meeting institutional coverage criteria. The Centers for Medicare & Medicaid Services made the following national coverage decision on 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 ... 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 ... 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.
Nationally non-covered indications include “Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial).”

**Regulatory Status**

Solid organ transplants are a surgical procedure and, as such, are 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. Solid organ transplants are included in these regulations.

**References**


205. Gruessner AC, Sutherland DE. Access to pancreas transplantation should not be restricted because of age: invited commentary on Schenker et al [commentary]. Transpl Int. Feb 2011;24(2):134-135. PMID 21208293


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<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>Date</td>
<td>Comments</td>
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<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>
</tr>
<tr>
<td>03/10/09</td>
<td>Replace Policy - Policy updated with literature search; references added. No change to policy statement.</td>
</tr>
<tr>
<td>02/09/10</td>
<td>Replace Policy - Policy updated with literature search. No change to policy statement.</td>
</tr>
<tr>
<td>01/11/11</td>
<td>Replace Policy - Policy updated with literature search. No change to policy statement.</td>
</tr>
<tr>
<td>01/06/12</td>
<td>Replace Policy – Policy updated with literature search; references added. No change to policy statement.</td>
</tr>
<tr>
<td>12/03/12</td>
<td>Update title to Related Policy 7.03.11.</td>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<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>
</tr>
<tr>
<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>
</tr>
<tr>
<td>09/24/15</td>
<td>Coding update. ICD-9 Procedure codes removed; these are informational only.</td>
</tr>
<tr>
<td>01/12/16</td>
<td>Annual Review. Policy updated with literature search; references added. No change to the policy statement.</td>
</tr>
<tr>
<td>01/29/16</td>
<td>Coding update. Added HCPCS code S2152.</td>
</tr>
<tr>
<td>11/01/16</td>
<td>Update related policies. Removed 7.03.05 from related policies section as it was</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>deleted</td>
<td>(contents moved to 7.03.04).</td>
</tr>
<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>
</tr>
<tr>
<td>04/14/17</td>
<td>Coding update; added HCPCS code S2060.</td>
</tr>
<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>
</tr>
<tr>
<td>11/01/18</td>
<td>Annual Review, approved October 26, 2018. Policy updated with literature review through June 2018; references 42, 51, 56, 82, 87, 89, 94, 109, 111, 118, 120,136, 158, 164, 178,183, 184, and 201 added. Examples of end-stage cardiac and pulmonary diseases added for clarity under heart and lung transplant. Etiologies of end-stage liver disease added for clarity, polycystic disease of the liver, unresectable hilar cholangiocarcinoma, pediatric patients with nonmetastatic hepatoblastoma are added as medically necessary indications for liver transplantation. Indications for liver retransplantation were added. Indications where liver transplantation is not medically necessary or is considered investigational were added, otherwise policy statements unchanged.</td>
</tr>
</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.
Discrimination is Against the Law

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 file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

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).


Premera Blue Cross

This notification may contain important information that you need to consider. Specific dates are noted in this notice. It is possible that this notice contains key dates.

If you have questions or concerns about the information in this notice, please call 800-722-1471 (TTY: 800-842-5357) or visit www.premerablue.com.

Română (Romanian):

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть ключевые даты. Вам, возможно, потребуется привет к определенным предельным срокам для сохранения страховочного покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощи на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

ไทย (Thai):
ประกาศนี้มีข้อมูลสําคัญ ถึงการขอการชดเชยหรือการขอความช่วยเหลือเกี่ยวกับการบริการเพื่อสุขภาพของ Premera Blue Cross และการมีสิทธิ์ในการค้นหา คุณจะต้องทราบถึง ด้านการส่งเสริมการรักษาพยาบาลที่มีสิทธิ์จะต้องการการสนับสนุนหรือการช่วยเหลือที่ไม่ได้รับ โปรดเรียก 800-722-1471 (TTY: 800-842-5357)

українська (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховочного покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити впевнені кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):