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 kidney 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.
Transplant Medical Necessity

**Kidney transplant**
Kidney transplants with either a living or deceased (cadaver) donor may be considered medically necessary for patients with documented end-stage renal disease.

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

*Note:* See Related Information

### Transplant Investigational

**All other situations**
Kidney transplant is considered investigational in all other situations not described above.

**HCV-viremic (hepatitis C) organs**
The transplantation of HCV-viremic solid organs (kidney, lung, heart, liver, small bowel, pancreas) to an HCV non-viremic recipient combined with direct-acting antiviral treatment for HCV is considered investigational.

### Documentation Requirements

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Office visit notes that contain the relevant history and physical documenting the patient has end-stage renal disease.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></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>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
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<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>

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### Related Information

**Renal-Specific Criteria**

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.

**Contraindications**

Potential contraindications to solid organ transplant (subject to the judgment of the transplant center):

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

Benefit Application

See member’s plan contract language for organ transplant benefits and specific benefits related to transport, lodging, and donor services. Please note limitations in coverage based on the transplant benefit, if applicable.

Evidence Review

Description

Kidney transplant, a treatment option for end-stage renal disease (ESRD), involves the surgical removal of a kidney from a cadaver, living-related donor, or living-unrelated donor and transplantation into the recipient.

Background

**End-Stage Renal Disease**

ESRD refers to the inability of the kidneys to perform their functions (ie, filtering wastes and excess fluids from the blood). ESRD, which is life-threatening, is also known as stage 5 chronic renal failure and is defined as a glomerular filtration rate less than 15 mL/min/1.73 m².¹

Treatment

Dialysis is an artificial replacement for some kidney functions. Dialysis is used as a supportive measure in patients who do not want kidney transplants or who are not transplant candidates; it can also be used as a temporary measure in patients awaiting a kidney transplant.

Kidney transplant, using kidneys from deceased or living donors, is an accepted treatment of ESRD. Based on data from the Organ Procurement and Transplantation Network, in 2017, over 10,300 kidney transplants were performed in the U.S. Since 1988, the cumulative number of
kidney transplants is over 435,500. Of the cumulative total, 66% of the kidneys came from deceased donors and 34% from living donors.

Combined kidney and pancreas transplants and management of acute rejection of kidney transplant using either intravenous immunoglobulin or plasmapheresis are discussed in separate medical policies.

Summary of Evidence

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. The 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 a kidney retransplant from a living donor or deceased (cadaveric) donor, the evidence includes registry data and case series. The 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 survival rates ranging from 87% to 96%) for appropriately selected patients. Kidney retransplantation is contraindicated for patients for whom the procedure is expected to be futile due to comorbid disease or for 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 are HCV non-viremic who have end-stage renal disease and are candidates for a kidney transplant the evidence for the use of HCV viremic donor organs as an alternative to continuing dialysis or other appropriate treatment and remaining on the transplant wait-list consists of preliminary results of two open-label nonrandomized trials (THINKER and EXPANDER). The primary outcomes were sustained virologic response (SVR) and graft function and survival. Major adverse events attributable to the selected HCV direct-acting antiviral agents (DAA) regimen was also assessed. To date, the experience of 30 participants has
been reported in the literature. Participants generally had comparable demographic characteristics. The studies differed in whether or not donor kidneys were genotyped in advance of transplantation. Appropriate DAA regimens were chosen to match genotype or pangenotypic was used. There were differences in the timing of administration of the DAA regimen, but all participants were followed to ascertain the need for extension of the original regimen or addition of another drug. All recipients showed evidence of HCV nucleic acid positivity and viral loads were determined in some instances. All recipients had SVR by the completion of the appropriate DAA regimen with the longest follow-up out to 12 months in 10 participants. There were no reports of allograft rejection or renal function abnormalities. Transient elevations in liver transaminases were reported but not in all participants. Assessment of quality of life (QOL) by the standard patient-reported measures in the first ten participants of the THINKER cohort indicated that QOL was initially diminished in the early postoperative period. At 12 months, the physical component score of the RAND-36 questionnaire improved beyond baseline but the mental component score returned to baseline. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>NCT03500315</td>
<td>HOPE in Action Prospective Multicenter, Clinical Trial of Deceased HIVD+ Kidney Transplants for HIV+ Recipients</td>
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<td>Aug 2022</td>
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<tr>
<td>NCT02669966</td>
<td>Live Kidney Donors with Positive Anti-HCV Antibody, But Negative HCV PCR</td>
<td>6</td>
<td>Jun 2020</td>
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<td>NCT02945150</td>
<td>Preemptive Treatment with Grazoprevir and Elbasvir for Donor HCV Positive to Recipient HCV Negative Kidney Transplant</td>
<td>40</td>
<td>Sept 2020</td>
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<td>NCT02743897</td>
<td>Open-Labeled Trial of Zepatier For Treatment of Hepatitis C-Negative Patients Who Receive Kidney Transplants from Hepatitis C-Positive Donors (THINKER)</td>
<td>75</td>
<td>Dec 2021</td>
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<tr>
<td>NCT No.</td>
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<td>Planned Enrollment</td>
<td>Completion Date</td>
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<tr>
<td>-----------</td>
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<tr>
<td>NCT03801707</td>
<td>An Open Label, Prospective, Interventional, Proof of Concept Study to Evaluate the Feasibility and Safety of Kidney Transplant from HCV Positive Donors into HCV Negative Recipient Using Sofosbuvir/Velpatasvir as a Treatment for Post-Transplant HCV Transmission</td>
<td>25</td>
<td>Jan 2022</td>
</tr>
</tbody>
</table>

NCT: National clinical trial

Practice Guidelines and Position Statements

*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.\(^{23}\) 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 permitting the use of this group of organ donors.

*The American Society of Transplantation*

The American Society of Transplantation (2017) convened a consensus conference of experts to address issues related to the transplantation of hepatitis C virus (HCV) viremic solid organs into HCV non-viremic recipients and concluded that the transplantation of organs from HCV viremic donors into HCV-negative recipients should be conducted only under monitored IRB-approved protocols and studies.
Medicare National Coverage

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.

Regulatory Status

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

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

References


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/01/19</td>
<td>New policy, approved October 4, 2019. Content previously addressed in policy 7.03.509. Policy created with literature review through June 2019. Kidney transplantation may be considered medically necessary when criteria are met, considered investigational when criteria are not met. Policy statement on transplantation of HCV viremic organs is taken from BCBSA policy 7.03.14.</td>
</tr>
<tr>
<td>04/01/20</td>
<td>Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.</td>
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<tr>
<td>06/10/20</td>
<td>Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.</td>
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**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). ©2020 Premera All Rights Reserved.

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  • Information written in other languages

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Toll free 855-332-4535, Fax 425-918-5952, 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 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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800-722-1471 (TTY: 800-842-5357)

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Français (French):

Deutsche (German):

Hmoob (Hmong):

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