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MEDICAL POLICY – 7.03.01

Kidney Transplant

BCBSA Ref. Policy:	7.03.01	
Effective Date:	Nov. 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	Oct. 7, 2024	7.03.02 Allogeneic Pancreas Transplant
Replaces:	Extracted from 7.03.509	

Select a hyperlink below to be directed to that section.

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

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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.

Policy Coverage Criteria

Transplant	Medical Necessity
Kidney transplant	**Kidney transplants with either a living or cadaver donor may be considered medically necessary for carefully selected individuals with documented end-stage renal disease.** **Kidney retransplant after a failed primary kidney transplant may be considered medically necessary in individuals 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.**

Documentation Requirements
The individual'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 individual has end-stage renal disease.

Coding

Code	Description
CPT	
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
HCPCS	
S2065	Simultaneous pancreas kidney transplantation
S2152	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,

Code	Description
	diagnostic, emergency, and rehabilitative services, and the number of days of pre and posttransplant care in the global definition

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

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 individuals; however, consideration for listing for renal transplant may start well before the creatinine level reaches this point, based on the anticipated time that an individual 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

Solid organ transplantation offers a treatment option for individuals with different types of end-stage organ failure that can be lifesaving or provide significant improvements to an individual's quality of life.[1] Many advances have been made in the last several decades to reduce perioperative complications. Available data support improvement in long-term survival as well as improved quality of life particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Individuals are prioritized for transplant by mortality risk and severity of illness criteria developed by Organ Procurement and Transplantation Network (OPTN) and United Network of Organ Sharing (UNOS).

Kidney Transplant

In 2022, 46,623 transplants were performed in the US procured from almost 39,670 deceased donors and 6,948 living donors.[2] Kidney transplants were the most common procedure with 27,332 transplants performed from both deceased and living donors in 2023. Since 1988, the

cumulative number of kidney transplants is 581,744.[3] Of the cumulative total, approximately 67% of the kidneys came from deceased donors and 33% from living donors.

Kidney transplant, using kidneys from deceased or living donors, is an accepted treatment of end-stage renal disease (ESRD). ESRD refers to the inability of the kidneys to perform their functions (i.e., filtering wastes and excess fluids from the blood). ESRD, which is life-threatening, is also known as chronic kidney disease stage 5 and is defined as a glomerular filtration rate (GFR) less than 15 mL/min/1.73 m^2.[4] Individuals with advanced chronic kidney disease, mainly stage 4 (GFR 15 to 29 mL/min/1.73 m^2) and stage 5 (GFR <15 mL/min/1.73 m^2), should be evaluated for transplant.[5] Being on dialysis is not a requirement to be considered for kidney transplant. Severe non-compliance and substance abuse serve as contraindications to kidney transplantation but even those could be overcome with clinician support and individual motivation. All kidney transplant candidates receive organ allocation points based on waiting time, age, donor-recipient immune system compatibility, prior living donor status, distance from donor hospital, and survival benefit.[6,7]

Combined kidney and pancreas transplants and management of acute rejection of kidney transplant using either intravenous immunoglobulin or plasmapheresis are discussed in separate 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 individuals and significantly higher survival rates for individuals undergoing kidney transplant compared with those who remained on a waiting list. Kidney transplantation is contraindicated for individuals in whom the procedure is expected to be futile due to comorbid disease or in whom post transplantation care is expected to significantly worsen comorbid conditions. The evidence is sufficient to determine that the technology results in an 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 (e.g., 5-year survival rates ranging from 87% to 96%) for appropriately selected individuals. Kidney retransplantation is contraindicated for individuals for whom the procedure is expected to be futile due to comorbid disease or for whom post transplantation care is expected to significantly worsen comorbid conditions. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

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

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04182607	Donor Outcomes Following Hand-Assisted And Robotic Living Donor Nephrectomy: A Retrospective Review	240	Nov 2022
Unpublished			
NCT03500315	HOPE in Action Prospective Multicenter, Clinical Trial of Deceased HIVD+ Kidney Transplants for HIV+ Recipients	209	May 2024

NCT: National clinical trial

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Transplant Surgeons et al

In 2011, the American Society of Transplant Surgeons, the American Society of Transplantation, the Association of Organ Procurement Organizations, and the UNOS issued a joint position statement recommending modifications to the National Organ Transplant Act of 1984.[30] 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 individuals already infected with HIV. In 2013, the HIV Organ Policy Equity Act permitted the use of this group of organ donors.

Medicare National Coverage

The Medicare Benefit Policy Manual includes a chapter on ESRD.[31] A section on identifying candidates for transplantation (140.1) states:

> "After a patient is diagnosed as having ESRD, the physician should determine if the patient is suitable for transplantation. If the patient is a suitable transplant candidate, a live donor transplant is considered first because of the high success rate in comparison to a cadaveric transplant. 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

Solid organ transplants are a surgical procedure and, as such, are not subject to regulation by the US Food and Drug Administration (FDA).

The FDA 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 organs used for transplantation are subject to these regulations.

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History

Date	Comments
11/01/19	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.

Date	Comments
04/01/20	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.
06/10/20	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.
11/01/20	Annual Review, approved October 22, 2020. Policy updated with literature review through June, 2020; references added. Policy statements unchanged.
11/01/21	Annual Review, approved October 5, 2021. Policy updated with literature review through July 1, 2021; no references added. Policy statements unchanged.
11/01/22	Annual Review, approved October 10, 2022. Policy updated with literature review through June 10, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
10/01/23	Annual Review, approved September 25, 2023. Policy updated with literature review through June 14, 2023; no references added. Removed the policy statement regarding the transplantation of HCV-viremic solid organs to an HCV non-viremic recipient combined with direct-acting antiviral treatment for HCV is considered investigational. Otherwise, policy statements unchanged.
11/01/24	Annual Review, approved October 7, 2024. Policy updated with literature review through June 14, 2024; no references added. Policy statements unchanged.

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). ©2024 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.