BlueCross BlueShield Federal Employee Program.

# FEP Medical Policy Manual

## FEP 7.03.01 Kidney Transplant

### Effective Policy Date: January 1, 2023

### Original Policy Date: March 2012

### Related Policies:

7.03.02 - Allogeneic Pancreas Transplant
8.01.02 - Chelation Therapy for Off-Label Uses

# Kidney Transplant

## Description

## Description

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

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 (ie, 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,] Patients 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 patient 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,]

# OBJECTIVE

The objective of this evidence review is to determine situations in which a kidney transplant or kidney retransplant is medically appropriate and improves net health outcomes.

# POLICY STATEMENT

Kidney transplants with either a living or cadaver donor may be considered **medically necessary** for carefully selected individuals with 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.

Kidney transplant is considered **investigational** in all other situations.

# POLICY GUIDELINES

## 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

## 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.

# BENEFIT APPLICATION

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

# FDA 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 (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.

# RATIONALE

## 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. Relevant outcomes are overall survival (OS), 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 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. Relevant outcomes are OS, 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 an improvement in the net health outcome.

# SUPPLEMENTAL INFORMATION

## Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' 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 wait 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.

## U.S. Preventive Services Task Force Recommendations

Not applicable.

## 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."

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

| Date | Action | Description |
|---|---|---|
| March 2012 | New policy | |
| September 2013 | Replace policy | Policy reviewed with literature search through April 4, 2013. References 1, 3-5, 10-13 added. Statement added that kidney retransplant after a failed primary kidney transplant may be considered medically necessary. |
| September 2014 | Replace policy | Policy updated with literature review. References 5, 10-12, and 16 added. ICD codes for covered conditions moved to Policy Guidelines section. Statement added that kidney transplant is considered not medically necessary in all other situations. |
| September 2015 | Replace policy | Policy updated with literature review; references 7-8, 12 and 14 added. Policy statements unchanged. |
| December 2018 | Archive policy | Policy updated with literature review through June 21, 2018; references 5, 7, and 12-13 added; reference 2 and 23 updated. Policy statements unchanged. Policy archived. |
| December 2021 | Reactivate policy | Reactivate Policy. Kidney transplant, living or cadaver donor, and kidney re-transplant medically necessary with criteria. |
| December 2022 | Replace policy | Policy updated with literature review through June 10, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. |