



FEP Medical Policy Manual

FEP 7.03.01 Kidney Transplant

Annual Effective Policy Date: January 1, 2024

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 m².⁴ Patients with advanced chronic kidney disease, mainly stage 4 (GFR 15 to 29 mL/min/1.73 m²) and stage 5 (GFR <15 mL/min/1.73 m²), 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 1 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."

REFERENCES

1. Black CK, Termanini KM, Aguirre O, et al. Solid organ transplantation in the 21 st century. *Ann Transl Med.* Oct 2018; 6(20): 409. PMID 30498736
2. United Network for Organ Sharing (UNOS). Transplant trends. Updated June 6, 2023; <https://unos.org/data/transplant-trends/>. Accessed June 14, 2023
3. Organ Procurement and Transplantation Network. View Data Reports. n.d.; <https://optn.transplant.hrsa.gov/data/view-data-reports/>. Accessed June 14, 2023.
4. National Kidney Foundation. Glomerular Filtration Rate (GFR). n.d.; <https://www.kidney.org/atoz/content/gfr>. Accessed June 14, 2023.
5. US Department of Health & Human Services. Educational guidance on patient referral to kidney transplantation. September 2015; <https://optn.transplant.hrsa.gov/resources/guidance/educational-guidance-on-patient-referral-to-kidney-transplantation/>. Accessed June 14, 2023.
6. United Network for Organ Sharing (UNOS). How we match organs. 2023. <https://unos.org/transplant/how-we-match-organs/>. Accessed June 14, 2023.
7. Organ Procurement and Transplantation Network (OPTN). OPTN policies. Updated March 16, 2023. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf. Accessed June 14, 2023.
8. Chaudhry D, Chaudhry A, Peracha J, et al. Survival for waitlisted kidney failure patients receiving transplantation versus remaining on waiting list: systematic review and meta-analysis. *BMJ.* Mar 01 2022; 376: e068769. PMID 35232772
9. Krishnan N, Higgins R, Short A, et al. Kidney Transplantation Significantly Improves Patient and Graft Survival Irrespective of BMI: A Cohort Study. *Am J Transplant.* Sep 2015; 15(9): 2378-86. PMID 26147285
10. Querard AH, Foucher Y, Combescore C, et al. Comparison of survival outcomes between Expanded Criteria Donor and Standard Criteria Donor kidney transplant recipients: a systematic review and meta-analysis. *Transpl Int.* Apr 2016; 29(4): 403-15. PMID 26756928
11. Pestana JM. Clinical outcomes of 11,436 kidney transplants performed in a single center - Hospital do Rim. *J Bras Nefrol.* 2017; 39(3): 287-295. PMID 28902233
12. Segev DL, Muzaale AD, Caffo BS, et al. Perioperative mortality and long-term survival following live kidney donation. *JAMA.* Mar 10 2010; 303(10): 959-66. PMID 20215610
13. Muller E, Barday Z, Mendelson M, et al. HIV-positive-to-HIV-positive kidney transplantation--results at 3 to 5 years. *N Engl J Med.* Feb 12 2015; 372(7): 613-20. PMID 25671253
14. Locke JE, Reed RD, Mehta SG, et al. Center-Level Experience and Kidney Transplant Outcomes in HIV-Infected Recipients. *Am J Transplant.* Aug 2015; 15(8): 2096-104. PMID 25773499
15. Locke JE, Mehta S, Reed RD, et al. A National Study of Outcomes among HIV-Infected Kidney Transplant Recipients. *J Am Soc Nephrol.* Sep 2015; 26(9): 2222-9. PMID 25791727
16. Locke JE, Gustafson S, Mehta S, et al. Survival Benefit of Kidney Transplantation in HIV-infected Patients. *Ann Surg.* Mar 2017; 265(3): 604-608. PMID 27768622
17. Sawinski D, Forde KA, Eddinger K, et al. Superior outcomes in HIV-positive kidney transplant patients compared with HCV-infected or HIV/HCV-coinfected recipients. *Kidney Int.* Aug 2015; 88(2): 341-9. PMID 25807035
18. Zheng X, Gong L, Xue W, et al. Kidney transplant outcomes in HIV-positive patients: a systematic review and meta-analysis. *AIDS Res Ther.* Nov 20 2019; 16(1): 37. PMID 31747972
19. Working Party of the British Transplantation Society. Kidney and Pancreas Transplantation in Patients with HIV. Second Edition (Revised). 2017. https://bts.org.uk/wp-content/uploads/2017/04/02_BTS_Kidney_Pancreas_HIV.pdf. Accessed June 14, 2023.
20. Fabrizi F, Martin P, Dixit V, et al. Meta-analysis of observational studies: hepatitis C and survival after renal transplant. *J Viral Hepat.* May 2014; 21(5): 314-24. PMID 24716634
21. Gill JS, Lan J, Dong J, et al. The survival benefit of kidney transplantation in obese patients. *Am J Transplant.* Aug 2013; 13(8): 2083-90. PMID 23890325
22. Pieloch D, Dombrovskiy V, Osband AJ, et al. Morbid obesity is not an independent predictor of graft failure or patient mortality after kidney transplantation. *J Ren Nutr.* Jan 2014; 24(1): 50-7. PMID 24070588
23. Kwan JM, Hajjiri Z, Metwally A, et al. Effect of the Obesity Epidemic on Kidney Transplantation: Obesity Is Independent of Diabetes as a Risk Factor for Adverse Renal Transplant Outcomes. *PLoS One.* 2016; 11(11): e0165712. PMID 27851743
24. Kervinen MH, Lehto S, Helve J, et al. Type 2 diabetic patients on renal replacement therapy: Probability to receive renal transplantation and survival after transplantation. *PLoS One.* 2018; 13(8): e0201478. PMID 30110346

25. Lim WH, Wong G, Pilmore HL, et al. Long-term outcomes of kidney transplantation in people with type 2 diabetes: a population cohort study. *Lancet Diabetes Endocrinol.* Jan 2017; 5(1): 26-33. PMID 28010785
26. Barocci S, Valente U, Fontana I, et al. Long-term outcome on kidney retransplantation: a review of 100 cases from a single center. *Transplant Proc.* May 2009; 41(4): 1156-8. PMID 19460504
27. Kainz A, Kammer M, Reindl-Schwaighofer R, et al. Waiting Time for Second Kidney Transplantation and Mortality. *Clin J Am Soc Nephrol.* Jan 2022; 17(1): 90-97. PMID 34965955
28. Gupta M, Wood A, Mitra N, et al. Repeat Kidney Transplantation After Failed First Transplant in Childhood: Past Performance Informs Future Performance. *Transplantation.* Aug 2015; 99(8): 1700-8. PMID 25803500
29. Shelton BA, Mehta S, Sawinski D, et al. Increased Mortality and Graft Loss With Kidney Retransplantation Among Human Immunodeficiency Virus (HIV)-Infected Recipients. *Am J Transplant.* Jan 2017; 17(1): 173-179. PMID 27305590
30. American Society of Transplant Surgeons (ASTS), The American Society of Transplantation (AST), The Association of Organ Procurement Organizations (AOPO), et al. Statement on transplantation of organs from HIV-infected deceased donors. 2011; https://asts.org/docs/default-source/position-statements/transplantation-of-organs-from-hiv-infected-deceased-donors-july-22-2011.pdf?sfvrsn=fbae5a20_4. Accessed June 14, 2023.
31. Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual: Chapter 11 - End Stage Renal Disease (ESRD). 2019; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf>. Accessed June 14, 2023.

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.
December 2023	Replace policy	Policy updated with literature review through June 14, 2023; no references added. Policy statements unchanged.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.