MEDICAL POLICY

Medical Policy Title	**Kidney Transplantation**
Policy Number	**07.02.04**
Current Effective Date	April 17, 2025
Next Review Date	April 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Kidney transplants are **medically appropriate** for candidates with documented progressive end stage renal disease (ESRD) when **EITHER** of the following indications are present:

   A. A measured (actual urinary collection) creatinine clearance level or calculated glomerular filtration rate (GFR) (or another reliable formula) less than or equal to 20ml/min; **or**

   B. The initiation of dialysis.

II. Kidney retransplants after a failed primary kidney transplant are considered **medically necessary** when the criteria in Policy Statement I are met.

III. The following conditions are **absolute contraindications** to kidney transplantation:

   A. Presence of malignancy (other than non-melanoma skin cancers), unless malignancy has been completely resected, or unless (upon medical review) it is determined that malignancy has been treated with a small likelihood of recurrence and acceptable future risks;

   B. Ongoing or recurring infections that are not effectively treated;

   C. Serious cardiac or pulmonary, other ongoing comorbid conditions that create an inability to tolerate transplant surgery;

   D. Demonstrated non- adherence to medical recommendations, which places the organ at risk.

IV. Kidney transplantation is considered a **relative contraindication** in human immunodeficiency virus (HIV) positive individuals, unless **ALL** of the following criteria are met:

   A. CD4 count greater than 200 cells/mm3;

   B. Undetectable HIV-1 ribonucleic acid (RNA);

   C. On Stable anti-retroviral therapy for greater than three (3) months; **and**

   D. All other criteria within the policy are met.

RELATED POLICIES

Corporate Medical Policy

07.02.01 Pancreas Transplant: (Pancreas Transplant Alone, Pancreas Transplant after Kidney Transplant, Simultaneous Pancreas Kidney Transplant): Islet Cell Transplant

POLICY GUIDELINE(S)

I. Recipient Selection

A. Each individual considered for renal transplantation will have an evaluation completed by the transplant center for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the individual's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation. Candidates considered for transplant must be psychologically stable, demonstrate motivation and compliance, and have no ongoing problems with drug or alcohol abuse.

B. Nutritional issues are important predictors of surgical outcome. For candidates with BMI outside of the "normal range", documentation of dietary counseling will be required at the time of evaluation and while on the waiting list.

C. Diabetic complications often fall into the realm of relative contraindications (except for significant cardiovascular disease); however, renal transplantation is associated with improved survival in individuals with ESRD caused by type 1 diabetes mellitus. Individuals with diabetes may be candidates for combined kidney-pancreas transplantation.

II. Prior authorization requirements are contract dependent. Approvals for all transplants, including arrangements with an approved transplant center, may be required.

III. Pre-transplant evaluation documentation must include the following clinical information (if testing is unable to be performed, the rationale for not performing the testing must be included in the documentation):

A. Clinical Evaluation:

1. Confirmation of diagnosis;
2. Identification of comorbidities;
3. Treatment of co-morbidities;
4. Current assessment of co-morbidities; and
5. Consult notes (if applicable).

B. Psycho-Social Evaluation:

1. Karnofsky performance score; and/or Palliative Performance Scale (PPS) score; and
2. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol, or substance abuse).

C. Oral Health Evaluation

D. Lab Tests:

1. CBC, metabolic profile;

2. Serologies: CMV; Hepatitis B and C; and
3. HIV Testing.

E. Cardiac Assessment:

1. 12 Lead EKG;
2. Stress (exercise, nuclear, or dobutamine), and
3. Echo or MUGA Scan.

F. Pulmonary Assessment:

1. Chest x-ray;
2. Pulmonary function tests (PFTs) for high-risk respiratory failure (COPD, emphysema, alpha 1-antitrypsin deficiency, hepatopulmonary syndrome, or significant smoking history); and
3. Low-dose screening CT for individuals considered high-risk for lung cancer (e.g., 20- to 30-pack history of smoking).

G. Age-appropriate Screening Tests: Please refer to the U.S Preventive Services Task Force (USPSTF) [Internet] for list of age-appropriate screening guidelines (e.g., colorectal cancer screening, cervical cancer screening for guidance). [accessed 2025 Mar 4]. Available from: https://uspreventiveservicestaskforce.org/uspstf/

IV. Hepatitis C virus (HCV) infections are common among individuals with chronic renal failure and result in significant morbidity and mortality. Therefore, the assessment of hepatitis C virus infection in the potential recipient has a major clinical significance. HCV infections are associated with an increased risk of death, irrespective of whether the individual stays on dialysis or has a renal transplant. Transplantation has a beneficial, rather than adverse, effect on long-term survival in an anti-HCV-positive individual. An HCV-positive status is not a contradiction for renal transplantation.

V. A person who gives consent to be a live organ donor should be competent, willing to donate, free from coercion, medically and psychologically suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits, and alternative treatment available to the recipient. The benefits to both donor and recipient must outweigh the risks associated with the donation and transplantation for the living donor organ.

VI. Candidates may be wait-listed at more than one transplant center. Since waiting time priority is first calculated among candidates at all hospitals within the local donation area, listing at transplant centers in different local allocation areas is recommended. Requirements for multiple-listed candidates may vary among transplant centers. When possible, results of tests used in the evaluation for the transplant at one center should be used at subsequent centers where the individual is listed.

VII. Transplant re-authorization must be completed annually while actively waiting for a transplant. Re-authorization documentation must be within the past 11 months (unless specified) and include the following clinical information (if testing is unable to be performed, the rationale must be included in the documentation). If your health condition has not changed from the previous year some testing would not be applicable.

A. Clinical Evaluation:

1. Updated list of diagnoses to include identification of comorbidities, current assessment, and treatment plan.
2. Specialty consultation notes (if applicable).

C. Current functional ability as evidenced by current Karnofsky performance score (KPS); or Palliative Performance Scale (PPS) score.

D. Follow-up Oral Health Evaluation

E. Lab Tests:

1. CBC, metabolic profile;
2. Serologies: CMV Hepatitis B and C; and
3. HIV testing (If applicable).

F. Cardiac Assessment:

1. 12 Lead EKG (If applicable);
2. Stress (exercise, nuclear, or dobutamine) (If applicable); and
3. Echo or Muga scan (If applicable).

G. Pulmonary Assessment:

1. Chest x-ray (If applicable);
2. Pulmonary function tests (PFTs) for high-risk respiratory failure (COPD, emphysema, a-1-antitrypsin deficiency, hepatopulmonary syndrome, or significant smoking history); and
3. Low-dose screening CT for individuals considered high-risk for lung cancer (e.g., 20- to 30-pack history of smoking.

H. Age-appropriate Screening Tests: Please refer to the USPSTF [Internet] for a list of age-appropriate screening guidelines (e.g., colorectal cancer screening, cervical cancer screening for guidance). [accessed 2025 Mar 4]. Available from: https://uspreventiveservicestaskforce.org/uspstf/

DESCRIPTION

The kidneys are two bean-shaped organs located on each side of the spine just below the rib cage. Kidneys are about the size of a fist. Their main function is to filter blood toxins and transform the

waste into urine to be eliminated. When kidneys lose filtering abilities, harmful levels of fluid and waste accumulate in the body, which can result in kidney (renal) failure. Estimated glomerular filtration rate (eGFR) is a calculation used to estimate how well the kidneys are filtering certain products produced by the body. In adults, the normal eGFR number is usually 90-100. Which means that the kidney function is 90-100%. eGFR declines with age, even in people without kidney disease.

Kidney transplantation is considered a standard treatment option for a select group of individuals with progressive ESRD also known as Stage 5 kidney disease The National Kidney Foundation (NKF) states that Stage 5 chronic kidney disease is eGFR less than 15 for 3 months or more, or the individual is on dialysis. GFR estimate is considered the best measure of kidney function (NKF, 2023).

A kidney transplant consists of a surgical procedure that involves placing a healthy kidney from a living donor or deceased (cadaveric) donor into a person whose kidneys no longer function properly. Transplant recipients require life-long immunosuppression to prevent rejection. Individuals are prioritized for transplant by mortality risk and severity of illness criteria developed by the Organ Procurement and Transplantation Network (OPTN) and United Network of Organ Sharing (UNOS).

Living donor kidney transplant is the best option for ESRD individuals. Living donors can be related or unrelated to the recipient. Living kidney donation eliminates the recipient's need for waiting time on a national waiting list and can add psychological benefits to both donor and recipient. In the absence of a living donor, many transplanted kidneys come from deceased organ donors.

SUPPORTIVE LITERATURE

ESRD individuals without contraindications to a kidney transplant, regardless of if the person has a living donor or deceased donor has demonstrated reasonably high survival rates after kidneys are transplanted compared with those who remained on a waiting list (Black et al. 2018). According to UNOS (2025) kidney transplants were the most common organ transplanted from both deceased and living donors.

Chaudhry et al. (2022) published a systematic review that compared survival for waitlisted patients with kidney failure who received a transplant compared to those who remained on the transplant waiting list. A total of 48 observational studies were included in the systematic review, of which 18 studies were suitable for meta-analysis. Results demonstrated a 55% reduction in the risk of mortality in patients who received a transplant compared to those who remained on dialysis.

Kainz et al. (2022), retrospectively compared the association of time on the waitlist with survival of those who received a second transplant to those who remained on the waitlist. A total of 2346 individuals from the Austrian Dialysis and Transplant Registry and Eurotransplant was included in the study. Inclusion criteria were individuals with a failed first graft, were over the age of 18 years old, and waitlisted for a second kidney transplantation in Austria between the years of 1980 through 2019. Study results demonstrated that second kidney transplantation improved survival at 10 years of follow-up compared with remaining on the waitlist. The survival difference diminished in the individuals with longer wait times after loss of the first allograft. For individuals with a waitlist time for retransplantation of 1 year or less, gained 8.0 life months compared with those who remained on the waiting list for 8 years (e.g., 0.1 life month were gained).

Kidney Retransplant

Multiple issues influence the outcome of retransplant, with the most significant being the cause of the prior transplant failure. The significant advances in clinical management and newer immunosuppressive agents have improve short-term allograft function, but long-term allograft function continue to remain suboptimal.

Pediatric kidney transplant recipients will likely require a retransplant in their lifetime. Gupta et al. (2015) retrospectively analyzed OPTN data, focusing on patients who had an initial kidney transplant as children. A total of 2281 patients were identified who had their first transplant when they were younger than 18 years and a second kidney transplant at any age. In multivariate analysis, the length of first graft survival and age at second graft were significantly associated with second graft survival. Specifically, the first graft survival time of more than 5 years was associated with better second graft survival. However, patients who were between 15 and 20 years old at second transplant were at increased risk of second kidney graft failure compared with individuals in other age groups. It is likely that most pediatric renal allograft recipients will require one or more retransplants during their lifetime. Unfortunately, the use of a second or subsequent grafts in pediatric recipients has inferior long-term graft survival rates compared with initial grafts, with decreasing rates with each subsequent graft (Saeed et al., 2024).

PROFESSIONAL GUIDELINE(S)

The 2021 Chronic Kidney Disease Epidemiology Collaboration (2021 CKD-EPI) removed race as a variable from the GFR equation and recalibrated the other coefficients variables (e.g., age, sex, and serum creatinine). Subsequently, the National Kidney Foundation and American Society of Nephrology Task Force recommended that the 2021 CKD-EPI equation be implemented for eGFR reporting (Delgado et al., 2022).

OPTN requires all transplant hospitals to use race-neutral calculations when estimating a candidate's GFR for any purpose covered by OPTN policy. Kidney transplant programs are required to assess their waiting lists and correct wait times for any African American kidney candidates disadvantaged by having their kidney function overestimated because of the use of a race-inclusive calculation (OPTN, 2023).

Kidney Disease Improving Global Outcomes (KDIGO) 2024 Clinical Practice Guideline for the Evaluation and Management of CKD recommends considering planning for preemptive kidney transplantation or dialysis access in adults when the GFR is < 15-20ml/min per 1.734 m2 or risk of kidney replacement therapy (KRT) is greater than 40% 2 years.

REGULATORY STATUS

On October 19, 1984, the Congress of the United States (U.S.) approved the National Organ Transplant Act (NOTA). It established the framework for the U.S. organ transplant system and served as a model for development of other transplant networks worldwide. Through the establishment of OPTN, the law directed that organ allocation would be managed on a national basis and be developed through a unique public-private partnership. Since the initial network contract was

finalized in 1986, UNOS has served as the OPTN under contract with the U.S. Department of Health and Human Services (HHS).

The HIV Organ Policy Equity (HOPE) Act was enacted in November 2013 and amended regulations of NOTA. The amendment removed clinical research and institutional review board (IRB) requirements for transplantation of kidneys and livers from donors with HIV to recipients with HIV. The HOPE Act stated that participation in such clinical research should no longer be a requirement for transplantation of kidneys and livers from donors with HIV to recipients with HIV.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50370	Removal of transplanted renal allograft

Code	Description
50380	Renal auto-transplantation, reimplantation of kidney

HCPCS Codes

Code	Description
No codes	

ICD10 Codes

Code	Description
N18.1-N18.9	Chronic kidney disease (CKD) (code range)

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SEARCH TERMS

Kidney Transplant, Renal Transplant

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Kidney Transplantation.

Please refer to the following Medicare Benefit Policy Manual Chapter 11-End Stage Renal Disease (ESRD). Revised 257, 03/01/19. Medicare Benefit Policy Manual [accessed 2025 Mar 7]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.

- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
10/18/01, 06/20/02, 05/21/03, 02/19/04, 02/17/05, 01/19/06, 02/15/07, 01/17/08, 03/19/09, 03/18/10, 03/17/11, 02/16/12, 01/17/13, 02/20/14, 02/19/15, 03/17/16, 03/16/17, 03/15/18, 03/21/19, 03/19/20, 03/18/21, 03/17/22, 05/18/23, 04/18/24, 04/17/25	
Date	**Summary of Changes**
04/17/25	• Annual review; policy intent unchanged; references updated.
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date