

# MEDICAL POLICY

MEDICAL POLICY DETAILS	
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Product Disclaimer	<ul style="list-style-type: none"> <li>Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.</li> <li>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.</li> <li>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.</li> <li>If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</li> </ul>

## POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, kidney transplants for carefully selected candidates, who have documentation of progressive end-stage renal disease (ESRD) and no immediate life-threatening conditions, have been medically proven to be effective and, therefore, are considered **medically appropriate** for patients with **EITHER** of the following indications:
  - A. A measured (actual urinary collection) creatinine clearance level or calculated GFR or other reliable formula) less than or equal to 20ml/min;
  - B. The initiation of dialysis.
- II. Based upon our criteria and assessment of the peer-reviewed literature, kidney retransplant after a failed primary kidney transplant has been medically proven to be effective and, therefore, is considered **medically necessary** when the criteria in Policy Statement I are met.

## POLICY GUIDELINES

- 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 patient'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. Conditions that preclude proceeding to transplantation include, but are not limited to:

## Medical Policy: KIDNEY TRANSPLANTATION

Policy Number: 7.02.04

Page: 2 of 7

1. Metastatic cancer;
  2. 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;
  3. Ongoing or recurring infections that are not effectively treated;
  4. Serious cardiac or other ongoing insufficiencies that create an inability to tolerate transplant surgery;
  5. Demonstrated non-compliance, which places the organ at risk by not adhering to medical recommendations.
- D. Renal transplantation in the context of asymptomatic HIV infection is rapidly evolving in the setting of highly active antiretroviral therapy (HAART). Currently, the United Network for Organ Sharing (UNOS) states that asymptomatic HIV-positive patients should not necessarily be excluded from candidacy for organ transplantation. In 2001, the Clinical Practice Committee of the American Society of Transplantation proposed that the presence of AIDS could be considered a contraindication to kidney transplant unless the patient meets **ALL** of the following criteria:
1. CD4 count greater than 200 cells/mm<sup>3</sup>.
  2. Undetectable HIV-1RNA.
  3. On stable anti-retroviral therapy for greater than three months.
  4. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections, Kaposi's sarcoma, or other neoplasm); and
  5. All other criteria for transplantation.
- E. Diabetic complications often fall into the realm of relative contraindications (except for significant cardiovascular disease); however, renal transplantation is associated with improved survival in patients with ESRD caused by type 1 diabetes mellitus. Patients 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;
    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; and
    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

## Medical Policy: KIDNEY TRANSPLANTATION

Policy Number: 7.02.04

Page: 3 of 7

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) website for list of age-appropriate screening guidelines. [<https://uspreventiveservicestaskforce.org/uspstf/>] accessed 03/19/24.

IV. Hepatitis C virus (HCV) infections are common among patient 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 of the patient 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 patient. An anti-HCV-positive status is not a contradiction for renal transplantation.

### V. Living Donation

Any 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 patient is listed.

### VII. Re-Authorization

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).

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

C. Follow-up Oral Health Evaluation

#### D. Lab Tests:

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

#### E. Cardiac Assessment:

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

#### F. Pulmonary Assessment:

1. Chest x-ray (If applicable);
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) website for a list of age-appropriate screening guidelines. [<https://uspreventiveservicestaskforce.org/uspstf/>] accessed 03/19/24.

## **Medical Policy: KIDNEY TRANSPLANTATION**

**Policy Number: 7.02.04**

**Page: 4 of 7**

### **DESCRIPTION**

A kidney transplant is a surgery to place a healthy kidney from a living or deceased donor into a person whose kidneys no longer function properly. Solid organ transplantation offers a treatment option for patients with different types of end-stage organ failure that can be lifesaving or provide significant improvements to a patient's quality of life. Transplant recipients require life-long immunosuppression to prevent rejection. Patients 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).

The kidneys are two bean-shaped organs located on each side of the spine just below the rib cage. Each is about the size of a fist. Their main function is to filter and remove waste, minerals, and fluid from the blood by producing urine. When kidneys lose this filtering ability, harmful levels of fluid and waste accumulate in the body, which can raise blood pressure and result in kidney failure. The glomerular filtration rate (GFR) is considered the best measure of kidney function. ESRD is life-threatening and is defined as a GFR of less than 15 mL/min/1.73 m<sup>2</sup> (National Kidney Foundation, 2023). ESRD is treated by dialysis or kidney transplant. A new eGFR equation, the 2021 Chronic Kidney Disease Epidemiology Collaboration (2021 CKD-EPI) equation in which the race variable was removed and the coefficients for the other variables (age, sex, and serum creatinine) were recalibrated, was published (Inker, et al., 2021). 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). The Board of Directors of OPTN unanimously approved a measure to require transplant hospitals to use a race-neutral calculation when estimating a patient's level of kidney function. Effective July 27, 2022, OPTN now requires all transplant hospitals to use race-neutral calculations when estimating a candidate's GFR for any purpose covered by OPTN policy.

In the last 10 to 15 years, the incidence of ESRD in patients aged 65 years and older has doubled. Renal transplantation confers substantial survival advantages over dialysis for patients greater than age 60 years. During the first year of renal replacement treatment, transplant and dialysis have similar survival rates. However, from the second year onward transplantation has demonstrated significant benefit over dialysis in the older patient with ESRD who meets the other criteria for transplant. The beneficial effects of transplantation over dialysis begin to disappear when the average age exceeds 65 years. Re-transplantations are far more common in kidney transplantation than in other solid organ transplants. The age of the recipient and details of the kidney transplant may affect the need for a second, third, fourth, or even more kidney transplant. Despite progressive improvements in graft and patient survival after kidney transplantation over the last decades, an increasing number of patients are waitlisted for re-transplantation. Effective January 5, 2023, kidney programs are required to assess their waiting lists and correct waiting times for any Black kidney candidates disadvantaged by having their kidney function overestimated due to the use of a race-inclusive calculation (OPTN, 2023).

### **RATIONALE**

Kidney transplant is an established treatment option for patients with progressive or end-stage renal disease. Good outcomes have been achieved outside the investigational setting. Solid organ transplantation for candidates who are HIV-positive has long been controversial, due to the long-term prognosis for HIV positivity, and the impact of immunosuppression on HIV disease. Although HIV-positive transplant recipients may be a research interest of some transplant centers, the minimal data regarding long-term outcomes in these patients consists primarily of case reports and abstract presentations of liver and kidney recipients. Nevertheless, some transplant surgeons argue that HIV positivity is no longer an absolute contraindication to transplant, due to the advent of highly active antiretroviral therapy (HAART), which has markedly changed the natural history of the disease. HAART is a treatment regimen typically comprised of a combination of three or more antiretroviral drugs. HAART may also be called antiretroviral therapy (ART) or combination antiretroviral therapy (cART). A key cornerstone of HAART is the co-administration of different drugs that inhibit viral replication by several mechanisms so that the propagation of a virus with resistance to a single agent becomes inhibited by the action of the other two agents. Furthermore, UNOS has indicated that asymptomatic HIV-positive patients should not necessarily be excluded from candidacy for organ transplantation, stating, "A potential candidate for organ transplantation whose test for HIV is positive but who is in an asymptomatic state should not necessarily be excluded from candidacy for organ transplantation, but should be advised that he or she may be at increased risk of morbidity and mortality because of immunosuppressive therapy." In 2001, the Clinical Practice Committee of the

## Medical Policy: KIDNEY TRANSPLANTATION

Policy Number: 7.02.04

Page: 5 of 7

American Society of Transplantation proposed that the presence of AIDS could be considered a contraindication to kidney transplant unless the specific criteria were present (*refer to Policy Statement IIC*).

According to UNOS 2023, wait times for transplants vary, and not everyone who needs a transplant will get one because of the shortage of organs that are suitable for donation. Only slightly more than 50% of people on the waiting list will receive an organ within five years. After the initial transplant evaluation, it is recommended that the awaiting transplant recipient work closely with their transplant team to remain an active recipient on a transplant waiting list. The roles of various risk factors and comorbid conditions governing an individual's suitability for transplantation such as adherence, tobacco use, diabetes, obesity, perioperative issues, causes of kidney failure, infections, malignancy, pulmonary disease, cardiac and peripheral arterial disease, neurologic disease, gastrointestinal and liver disease, hematologic disease, and bone and mineral disorder are addressed within the policy guidelines.

### CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- ***CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.***
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

#### **CPT Codes**

<b>Code</b>	<b>Description</b>
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
50380	Renal autotransplantation, reimplantation of kidney

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#### **HCPCS Codes**

<b>Code</b>	<b>Description</b>
No codes	

## Medical Policy: KIDNEY TRANSPLANTATION

Policy Number: 7.02.04

Page: 6 of 7

### ICD10 Codes

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

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\*Key Article

### KEYWORDS

Kidney Transplant, Renal Transplant

**Medical Policy: KIDNEY TRANSPLANTATION**

**Policy Number: 7.02.04**

**Page: 7 of 7**

**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

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.

[<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf>] accessed 03/19/24.