MEDICAL POLICY

Excellus

SUBJECT: KIDNEY TRANSPLANT	EFFECTIVE DATE: 04/19/00 REVISED DATE: 08/16/01, 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
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- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and review of the peer-reviewed literature, kidney transplants for carefully selected candidates, who have documentation of progressive end-stage renal disease and no immediate life threatening conditions, has been medically proven to be effective and therefore is considered **medically necessary** for the following indications:

A. A measured (actual urinary collection) creatinine clearance level or calculated GFR (Cockcroft-Gault) or other reliable formula) less than or equal to 20ml/min; or

B. The initiation of dialysis.

II. 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. Conditions that preclude proceeding to transplantation include, but are not limited to:

1. Metastatic cancer;
2. Presence of malignancy (other than non-melanoma skin cancers), or unless malignancy has been completely resected, or unless (upon medical review) it is determined that malignancy has been treated with small likelihood of recurrence and acceptable future risks;
2. Ongoing or recurring infections that are not effectively treated;
3. Serious cardiac or other ongoing insufficiencies that create and inability to tolerate transplant surgery;
4. Demonstrated non-compliance, which places the organ at risk by not adhering to medical recommendations.

C. Renal transplantation in the context of asymptomatic HIV infection is rapidly evolving in the setting of highly active antiretroviral therapy (HAART). Currently, United Network for Organ Sharing (UNOS) states that asymptomatic HIV positive patients should not necessarily be excluded for candidacy for organ transplantation. In 2001, the Clinical Practice Committee of the American Society of Transplantation proposed the presence of AIDS could be considered a contraindication to kidney transplant unless ALL of the following criteria are met :

1. CD4 count greater than 200 cells/mm^3,
2. HIV-1RNA undetectable,
3. On stable anti-retroviral therapy greater than 3 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. Meets all other criteria for transplantation.

D. 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.

E. The presence of hepatitis C virus (HCV) infections is 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 an adverse effect on long term survival in an anti-HCV-positive patient. An anti-HCV-positive status is not a contradiction for renal transplantation.

F. In the last 10-15 years the incidence of ESRD in the patient 65 years of age and older has doubled. Renal transplantation confers substantial survival advantages over dialysis for patients greater than 60 years of age. During the first year of renal replacement treatment, transplant and dialysis have similar survival rates. But, from the second year onward transplantation has demonstrated significant benefit over dialysis in the older patient with ESRD who meet the other criteria for transplant. The beneficial effects of transplantation over dialysis begin to disappear at when the average age exceeds 65 years.

III. Re-Transplantation

Re-transplantation is far more common in kidney transplantation than in other solid organ transplants.

IV. 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.

POLICY GUIDELINES:

I. Prior Authorization is contract dependent. Approvals for all transplants, including arrangements with an approved transplant center, may be required.

II. Pre-transplant evaluation documentation could include the following clinical information. If testing is unable to be performed, the rationale for not performing the testing should 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;
5. Consult notes (if applicable).

B. Psycho-Social Evaluation:
1. Karnosfsky performance score;
2. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol or substance abuse).

C. Dental Evaluation.

D. Lab Tests:
1. CBC, metabolic profile;
2. Serologies: CMV,
3. Hepatitis B and C;
4. HIV Testing.

E. Cardiac Assessment:
1. 12 Lead EKG;
2. Stress echo or MUGA Scan.

F. Pulmonary Assessment:
   1. Chest x-ray;
   2. Pulmonary function tests (PFTs).
   3. Low dose screening CT for individuals considered high-risk for lung cancer (e.g., 20-30 pack history of smoking).

G. Age Appropriate Screening Tests:
   1. Age greater than or equal to 50 years:
      a. Colonoscopy (within 10 years); or
      b. Flexible sigmoidoscopy (within 5 years); or
      c. Guaiac stool testing (within 1 year); or
      d. Rationale of contraindication to testing (if applicable).
   2. Women age 21-70 years:
      a. Pap smear (within 3 years).
   3. Women age greater than or equal to 40 years:
      a. Mammogram (within 2 years).

DESCRIPTION:

A kidney transplant involves the surgical removal of a kidney from a cadaver donor or a matched living donor (related and unrelated) into a recipient for end-stage renal disease (ESRD).

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 that 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+ transplant recipients may be a research interest of some transplant centers, the minimal data regarding long-term outcome in these patients consist primarily of case reports and abstract presentations of liver and kidney recipients. Nevertheless, some transplant surgeons would 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. Furthermore, UNOS states that asymptomatic HIV+ patients should not necessarily be excluded for 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 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).

CODES: Number Description

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.

CPT:	50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
	50320	Donor nephrectomy; 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, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, 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	with recipient nephrectomy
50370	Removal of transplanted renal allograft
50380	Renal autotransplantation, reimplantation of kidney

HCPCS:	No codes	
ICD9:	585	Chronic kidney disease
ICD10:	N18.1-N18.9	Chronic kidney disease (CKD) (code range)

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*key article

KEY WORDS:

Kidney Transplant, Renal Transplant.

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 NCD Complete Guide to Medicare Benefits Policy Manual for Transplantation - Inpatient Hospital Services at the following website for Medicare Members: http://www.cms.hhs.gov/CertificationandComplianc/20_Transplant.asp