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1.0 Description of the Procedure, Product, or Service

Kidney transplantation is a surgical procedure to implant a healthy kidney into a recipient with kidney disease or kidney failure. Sources for donated kidneys include living donors (may be a blood relative or an unrelated donor) or from a donor that has recently died, but has not suffered kidney injury (cadaver donor). However, a kidney from a living donor is preferable to a cadaver organ because the waiting period is dramatically shorter and because the organ can be tested before transplant, usually function immediately after transplant, and last longer. Blood-group matched (ABO compatible) living-donor kidney transplantation is the gold standard.

Kidney transplants are second only to corneal transplant as the most common transplant operation in the United States. There are over 9,000 kidney transplants performed each year.

A kidney transplant is usually placed on one side or the other in the lower abdomen through an incision that is about eight or nine inches in length. The kidney's artery is connected to one of the recipient's pelvic arteries. The kidney's vein is connected to one of the veins in the recipient's pelvis. The ureter, the tube that drains urine from the kidney, is connected to the bladder or to one of the recipient's own ureters.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NC Health Choice (NCHC) recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

- a. NCHC covers kidney transplantation for a recipient when medically necessary and all of the following criteria are met:
 1. The recipient has any of the following conditions which cause end stage renal disease (inadequate kidney function to support life):
 - A. Obstructive uropathy;
 - B. Systemic lupus erythematosus;
 - C. Polyarteritis;
 - D. Wegener's granulomatosis;
 - E. Cortical necrosis;
 - F. Henoch-Schonlein purpura;
 - G. Hemolytic uremic syndrome;
 - H. Acute tubular necrosis;
 - I. Hypertensive nephrosclerosis;
 - J. Renal artery or vein occlusion;
 - K. Chronic pyelonephritis;
 - L. IGA nephropathy;
 - M. Anti-glomerular base-membrane disease;
 - N. Focal glomerulosclerosis;
 - O. Analgesic nephropathy;
 - P. Heavy metal poisoning;
 - Q. Glomerulonephritis;
 - R. Polycystic kidney disease;
 - S. Medullary cystic disease;
 - T. Nephritis;
 - U. Nephrocalcinosis;
 - V. Gout nephritis;
 - W. Amyloid disease;
 - X. Fabry's disease;
 - Y. Cystinosis;
 - Z. Oxalosis;
 - AA. Diabetes mellitus;
 - BB. Horseshoe kidney;
 - CC. Renal aplasia or hypoplasia;
 - DD. Wilm's tumor;
 - EE. Renal-cell carcinoma;
 - FF. Myeloma;
 - GG. Tuberosus sclerosis;
 - HH. Trauma requiring nephrectomy;
 - II. Scleroderma;
 - JJ. Sickle Cell disease;
 - KK. Cholesterol emboli syndrome;
 - LL. Urolithiasis;
 - MM. Asymptomatic human immunodeficiency virus (HIV)-positive recipients who meet the following criteria:
 - i. Cluster Differentiation 4 (CD4) count greater than 200 cells/mm-3 for more than 6 months;
 - ii. HIV-1 Ribonucleic acid (RNA) undetectable;
 - iii. On stable anti-retroviral therapy more than 3 months;

- iv. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm); and
 - v. Meets all the other criteria for transplantation.
- b. The recipient meets the eligibility criteria for the transplant center performing the procedure; and
 - c. The recipient and caregiver are willing and capable of following the post transplant treatment plan.

NOTE: A NCHC recipient who is prior approved for living donor, may also be considered eligible for cadaveric donor if donor availability changes.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

NCHC does not cover kidney (renal) transplantation for a recipient who has any one of the contraindications listed below:

- a. Clinical indications other than listed in **Subsection 3.2**;
- b. Active drug or alcohol abuse;
- c. Active tobacco use;
- d. Active, potentially life-threatening, malignancy;
- e. Active infection;
- f. Active vasculitis;
- g. Untreated or irreversible end-stage illnesses;
- h. Inability to comply with post-transplant regimen;
- i. Organs sold rather than donated to a recipient; or
- j. Artificial organs or human organ transplant service for which the cost is covered or funded by governmental, foundation, or charitable grants.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for kidney transplantation per 10A NCAC 220.0101. All applicable NCHC policies and procedures must be followed in addition to the ones listed in this procedure. Guidelines must be followed for transplant network or consortiums, if available.

Only those NCHC recipients accepted for transplantation by a transplantation center and eligible for transplant listing shall be considered for prior review.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers shall comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

FDA approved procedures, products, and devices for implantation must be utilized for kidney (renal) transplantation.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery-

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
12/1/11		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
12/1/11	Throughout	NCHC policy developed comparable to DMA Clinical Coverage Policy 11B-4
12/1/11	Section 5.1	Policy updated to reflect compliance with 10A NCAC 220.0101 excepting kidney transplant from prior approval requirement
12/1/11	Attachment A, Section I	Policy updated to reflect compliance with 10A NCAC 220.0101 excepting kidney transplant from prior approval requirement

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

Providers shall bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Code	Description
50300	Donor nephrectomy (including cold preservation) from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy(including cold preservation); open, from living donor
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
50547	Donor nephrectomy (including cold preservation), from living donor

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Acute Inpatient Hospital

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers shall bill their usual and customary charges.

I. Billing for Donor Expenses

Donor expenses for non-NCHC donors are billed on the recipient's transplant claim. Donor expenses for NCHC donors are billed on the donor's claim.

Cadaveric/Deceased Organ Donations

Donor expenses (procuring, harvesting, and associated surgical and laboratory costs) for cadaveric/deceased organ donations are covered for a kidney transplant.

Living Organ Donations

Donor expenses (procuring, harvesting, and associated surgical and laboratory costs) for living organ donations are covered for a kidney transplant. NCHC covers reimbursement only for the approved donor.