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1.0 Description of the Procedure, Product, or Service

Kidney (renal) 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 (renal) 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 (renal) 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

Medicaid recipients may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination** (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

****EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid Billing Guide: <http://www.ncdhhs.gov/dma/basicmed/>

EPSDT provider page: <http://www.ncdhhs.gov/dma/epsdt/>

3.0 When the Procedure, Product, or Service Is Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

3.1 General Criteria

Medicaid 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 statewide; 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. Medicaid 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. Tuberous 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.
 - d. Only those Medicaid recipients accepted for transplantation by a transplantation center and eligible for transplant listing should be considered. Guidelines must be followed for transplant network or consortiums, if available.

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

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

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, investigational, or part of a clinical trial.

4.2 Specific Criteria

Medicaid does not cover kidney transplantation for a Medicaid 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

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

5.1 Prior Approval

Prior approval is not required for kidney transplantation per 10A NCAC 220.0101
All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

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 Medicaid's qualifications for participation;
- b. be currently enrolled with N.C. Medicaid; 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

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

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, 1987

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/1/06	Sections 2.2	The special provision related to EPSDT was revised.
12/1/06	Sections 3.0	A note regarding EPSDT was added to this section.
12/1/06	Section 3.1	The coverage criteria was revised to indicate that the creatinine clearance rate of 30ml/min is applicable to patients with cadaveric/deceased donor requests and a creatinine rate of 20ml/min is applicable to patients with living donor requests. The creatinine clearance calculation method was revised to indicate that the Cockcroft-Gault formula is used for adults and the Schwartz and Counahan-Barratt Methods GFR method is used for children and adolescents up to 18 years of age. Items 34, 35, and 36 were added as criteria for coverage.
12/1/06	Section 3.2	The stipulation that living donor donations are only covered when the donor is a Medicaid recipient was deleted.
12/1/06	Section 3.2.1	This section was reformatted to address cadaveric/deceased organ donations
12/1/06	Section 3.2.2	This section was added to address living organ donations.
12/1/06	Sections 4.0	A note regarding EPSDT was added to this section.
12/1/06	Section 4.3	This section was added to address contraindications for living organ donations.
12/1/06	Attachment A	Billing instructions for living organ donations and cadaveric/deceased organ donations were

Date	Section Revised	Change
		added.
5/1/07	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.
5/1/07	Attachment A	Added the UB-04 as an accepted claims form.
12/1/11	Throughout	Policy was updated to include coverage criteria and requirements to meet current community standards of practice.
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 Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

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

One unit per day.

F. Place of Service

Acute inpatient hospital

G. Co-payments

Co-payments are required for kidney (renal) transplantation.

H. Reimbursement

Providers shall bill their usual and customary charges.

I. Billing for Donor Expenses

Donor expenses for non-Medicaid donors are billed on the Medicaid recipient's transplant claim using the recipient's Medicaid identification number. Donor expenses for Medicaid donors are billed on the Medicaid donor's claim using the donor's Medicaid identification number.

Medicaid reimburses only for the actual donor's expenses. Medicaid does not reimburse for unsuccessful donor searches.

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. Medicaid covers reimbursement only for the approved donor.