To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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Related Clinical Coverage Policies
Refer to https://medicaid.ncdhhs.gov/ for the related coverage policies listed below:
1A-34, End Stage Renal Disease (ESRD) Services
11B-7, Pancreas Transplant

1.0 Description of the Procedure, Product, or Service

Kidney (renal) transplantation is a surgical procedure to implant a healthy kidney into a beneficiary 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.

1.1 Definitions

1.1.1 Glomerular Filtration Rate (GFR)

GFR is a blood test used to check how well the kidneys are working. Specifically, it estimates how much blood passes through the glomeruli each minute. Glomeruli are the tiny filters in the kidneys that filter waste from the blood.

1.1.2 Chronic Kidney Disease (CKD)

Chronic kidney disease is defined according to the presence or absence of kidney damage and level of kidney function—irrespective of the type of kidney disease (diagnosis).

1.1.3 End Stage Renal Disease (ESRD)

End stage renal disease (ESRD) is the last stage (stage five) of chronic kidney disease (CKD). When CKD, polycystic kidney disease (PKD) or other kidney diseases develop into ESRD, dialysis or a kidney transplant is necessary to live.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(*The term "General" found throughout this policy applies to all Medicaid policies*)

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*).

b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service..

2.1.2 Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

a. Medicaid

None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. **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 beneficiary 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 practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or 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 beneficiary'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 beneficiary's right to a free choice of providers.

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

1. that is unsafe, ineffective, or experimental or investigational.
2. 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 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 meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health

problem, prevent it from worsening, or prevent the development of additional health problems.

b. **EPSDT and Prior Approval Requirements**

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide,* and on the EPSDT provider page. The Web addresses are specified below.

   NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

   EPSDT provider page: https://medicaid.ncdhhs.gov/

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid shall cover the procedure, product, or service related to this policy when 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 beneficiary'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 beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by Medicaid

a. Medicaid shall cover kidney transplantation (deceased or living donor) for a beneficiary who meets ALL the following criteria:
   1. Renal insufficiency with uremia or current end stage renal disease (ESRD) with poor renal function documented by progressive and irreversible deterioration in renal function over the previous six (6) consecutive months and ONE of the following:
      A. Currently on dialysis;
      B. In beneficiaries eighteen (18) years and older, the measured or calculated glomerular filtration rate (GFR) is < 20 mL/min; OR
      C. In beneficiaries seventeen (17) years and younger, the measured or calculated GFR is < 30 mL/min

2. The beneficiary has completed an evaluation and meets the eligibility criteria for the transplant center performing the procedure;
3. The beneficiary and caregiver are willing and capable of following the post-transplant treatment plan;
4. Kidney re-transplant after a failed primary kidney transplant may be considered medically necessary if a beneficiary meets the criteria for kidney transplantation.
5. If the beneficiary is human immunodeficiency virus (HIV)-positive, ALL the following additional criteria must be met:
   A. Cluster Differentiation 4 (CD4) count greater than 200 cells/mm-3 for more than six (6) consecutive months;
   B. HIV-1 Ribonucleic acid (RNA) undetectable;
   C. On stable anti-retroviral therapy more than three (3) consecutive months;
   D. No other complications from HIV (opportunistic infection, such as aspergillus, tuberculosis, coccidioses mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm); and
   E. Meets ALL the criteria listed in **Subsections 3.2.1(a)(1)(2)(3)(4)** for transplantation.

NOTE: The renal diseases responsible for CKD in children are different from those observed in adults. Congenital renal and urologic anomalies are the most common cause of CKD in children. Although there have been many advances in conservative renal replacement therapy, renal transplantation is the best treatment for children with end-stage renal disease (ESRD). For these reasons, children frequently undergo primary or preemptive transplantation, in which transplantation is the first mode of treatment for ESRD. When performed, this procedure most commonly involves a living donor who is related to the beneficiary.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

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

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid shall not cover the procedure, product, or service related to this policy when:

a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0;**
b. the beneficiary does not meet the criteria listed in **Section 3.0;**
c. the procedure, product, or service 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 Not Covered

4.2.1 Specific Criteria Not Covered by Medicaid

Medicaid do not cover kidney transplantation for a beneficiary who has any ONE of the contraindications listed below:

a. Clinical indications other than listed in **Subsection 3.2**;
b. If the procedure is expected to be futile due to co-morbid disease or if post-transplantation care is expected to significantly worsen co-morbid conditions;
c. Serious cardiac or other ongoing insufficiencies that create an inability to tolerate transplant surgery;
d. Active drug or alcohol use;
e. Active tobacco use;
f. Active, potentially life-threatening, malignancy;
g. Life threatening extra-renal congenital abnormalities;
h. Active infection;
i. Active vasculitis;
j. Untreated or irreversible end-stage illnesses;
k. Untreated coagulation disorder;
l. Inability to comply with post-transplant regimen;
m. Organs sold rather than donated to a beneficiary; or
n. Artificial organs or human organ transplant service for which the cost is covered or funded by governmental, foundation, or charitable grants.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Medicaid shall not require prior approval for cadaveric or living donor kidney transplantation.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.2.2 Specific

None Apply.

5.3 Additional Limitations or Requirements

a. FDA approved procedures, products, and devices for implantation must be used for kidney (renal) transplantation; and
b. Implants, products, and devices must be used according to all FDA requirements current at the time of surgery;

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; 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.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 1987

Revision Information:

Date	Section Revised	Change
07/01/2005	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
09/01/2005	Section 2.2	The special provision related to EPSDT was revised.
12/01/2005	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/01/2006	Sections 2.2	The special provision related to EPSDT was revised.
12/01/2006	Sections 3.0	A note regarding EPSDT was added to this section.
12/01/2006	Section 3.1	The coverage criterion 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.
12/01/2006	Section 3.2	The stipulation that living donor donations are only covered when the donor is a Medicaid beneficiary was deleted.
12/01/2006	Section 3.2.1	This section was reformatted to address cadaveric/deceased organ donations
12/01/2006	Section 3.2.2	This section was added to address living organ donations.
12/01/2006	Sections 4.0	A note regarding EPSDT was added to this section.
12/01/2006	Section 4.3	This section was added to address contraindications for living organ donations.
12/01/2006	Attachment A	Billing instructions for living organ donations and cadaveric/deceased organ donations were added.
05/01/2007	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for beneficiaries under 21 years of age.
05/01/2007	Attachment A	Added the UB-04 as an accepted claims form.
07/01/2010	Throughout	Session Law 2009-451, Section 10.31(a) Transition of NC Health Choice Program administrative oversight from the State Health Plan to the Division of Medical Assistance (DMA) in the NC Department of Health and Human Services.
12/01/2011	Throughout	NCHC policy developed comparable to DMA Clinical Coverage Policy 11B-4
12/01/2011	Throughout	Policy was updated to include coverage criteria and requirements to meet current community standards of

Date	Section Revised	Change
		practice.
12/01/2011	Section 5.1	Policy updated to reflect compliance with 10A NCAC 220.0101 exempting kidney transplant from prior approval requirement
12/01/2011	Attachment A, Section I	Policy updated to reflect compliance with 10A NCAC 220.0101 exempting kidney transplant from prior approval requirement
03/01/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
02/01/2018	Section 1.1	Definitions added for glomerular filtration rate (GFR), chronic kidney disease (CKD), and end stage renal disease (ESRD).
02/01/2018	Section 3.2.1	The criteria were revised to reflect coverage based on GFR and age rather than diagnosis. Verbiage added to address re-transplantation.
02/01/2018	Section 4.2.1	Specific criteria not covered expanded.
02/01/2018	Section 5.1	Prior approval requirement removed from live donor transplantations. Reference to 10A NCAC 220.0101 removed as it has expired.
02/01/2018	Section 5.2.1	Prior approval requirements removed.
02/01/2018	Section 5.3	FDA statements moved from Section 7.0 to this section.
02/01/2018	Section 7.1	Removed requirement that a statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices be retained.
02/01/2018	Attachment A	Added the UB-04 as an accepted claims form. Removed CPT codes.
03/15/2019	Table of Contents	Added, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP.”
03/15/2019	All Sections and Attachments	Updated policy template language.
01/06/2020	Table of Contents	Updated policy template language, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.”
01/06/2020	Attachment A	Added, “Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines”.
08/15/2023	All Sections and Attachments	Updated policy template language due to North Carolina Health Choice Program’s move to Medicaid. Policy posted 08/15/2023 with an effective date of 4/1/2023.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, NCTracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/83711)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.
If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Unlisted Procedure or Service
CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

F. Place of Service

Acute inpatient hospital.

G. Co-payments

For Medicaid refer to the NC Medicaid State Plan:
https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices

H. Reimbursement

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/

I. Billing for Donor Expenses

1. **Billing for Donor Expenses for Medicaid Beneficiaries**
   Donor transplant-related medical expenses are billed on the Medicaid beneficiary's transplant claim using the beneficiary's Medicaid identification number.

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

2. **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.

3. **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.