

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:

- 1C-2, Medically Necessary Routine Foot Care
- 1D-4, Core Services Provided in Federally Qualified Health Centers and Rural Health Clinics
- 1S-1, Genotyping and Phenotyping for HIV Drug Resistance Testing
- 1S-2, HIV Tropism Assay
- 1S-4, Genetic Testing
- 12-B, Human Immunodeficiency Virus Case Management
- 8A, Enhanced Mental Health and Substance Abuse Services
- 8B, Inpatient Behavioral Health Services, 8C, Outpatient Behavioral Health Services Provided by Direct-Enrolled Providers
- 8L, Mental Health/Substance Abuse Targeted Case Management
- 1E-5, Obstetrics
- 1E-7, Family Planning Services
- 1A-34, End Stage Renal Disease (ERSD) Services

1.0 Description of the Procedure, Product, or Service

A laboratory is a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

1.1 Definitions

Specimen collection is when tissue, blood, or urine is taken for diagnostic purposes.

Venipuncture is the puncture of a vein through the skin in order to withdraw blood for analysis, to start an intravenous drip, or to inject medication or a radiopaque dye.

Panels are a series of related lab tests to provide diagnosis of disease or an assessment of health.

Independent Laboratory is one that is independent both of an attending or consulting physician's office and of a hospital that meets at least the requirements to qualify as an emergency hospital.

Outpatient Hospital Laboratory is a hospital laboratory that furnishes services to hospital outpatients, persons who have not been admitted by the hospital as an inpatient but are registered on the hospital records as an outpatient and receive services (rather than supplies alone) from the hospital.

Referring Laboratory is a laboratory that receives a specimen to be tested and then refers the specimen to another laboratory for the performance of the laboratory test.

Reference Laboratory is a laboratory that receives a specimen from another, referring laboratory for testing and that actually performs the test.

Date of Service is the date the specimen was collected, not the date the test was run.

1.2 Clinical Laboratory Improvement Amendment (CLIA)

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of beneficiary test results regardless of where the test was performed.

The laboratory provider shall comply with 42 Code of Federal Regulations (CFR) §493.5 Categories of tests by complexity.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term “General” found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC 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.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

- a. **Medicaid**
None Apply.
- b. **NCHC**
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/>

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

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 and NCHC 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 both Medicaid and NCHC

Medicaid and NCHC shall cover medically necessary laboratory services ordered by a physician or other licensed practitioner in the care and treatment of the beneficiary. The performing provider or laboratory shall have the required CLIA certifications.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC 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 and NCHC 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 both Medicaid and NCHC

Medicaid and NCHC shall not cover Laboratory Services in the following situations:

- a. VDRL screening performed in conjunction with a premarital screening.
- b. Paternity testing.
- c. Handling or conveyance of specimens.
- d. The procedure is performed for treatment and testing for infertility.
- e. Services for which the performing provider does not have appropriate CLIA certifications.
- f. Fungal cultures and KOH (potassium (K), oxygen (O), and hydrogen (H)) preparation for routine foot care. Refer to clinical coverage policy 1C-2, *Medically Necessary Routine Foot Care*, website at <https://medicaid.ncdhhs.gov/>, for additional information.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 1. No services for long-term care.
 2. No nonemergency medical transportation.
 3. No EPSDT.
 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

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

5.1 Prior Approval

Medicaid and NCHC shall not require prior approval for laboratory services.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.2.2 Specific

None Apply.

5.3 Venipuncture and Specimen Collection

Medicaid and NCHC shall allow venipuncture specimen collection to the provider who extracted the specimen only when it is sent to an independent laboratory for testing and no testing is done in the office.

5.4 Date of Service

The date of service is the date the specimen was collected, not the date the test was run. For specimens collected over a period that spans two calendar days, the date of service is the date the collection ended.

5.5 Pap Test

Medicaid and NCHC shall cover a Pap test as stated in clinical coverage policy 1E-7 *Family Planning Services*, at <https://medicaid.ncdhhs.gov/>

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 or NCHC 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.

Note: The laboratory provider shall comply with 42 CFR Part §493 Laboratory Requirements.

6.1 Requirements

Medicaid and NCHC require all laboratories to have their CLIA certification number on file to receive reimbursement for any laboratory procedures. Physicians are reminded that they only bill for those tests for which they are certified.

Providers who have questions regarding CLIA Certification can contact the Division of Health Service Regulation Acute and Home Care Licensure and Certification and CLIA Program at 919-855-4620 or the website at <https://www.ncdhhs.gov/>

Providers can view information on the Centers for Medicare and Medicaid Services (CMS) website for CLIA and Categorization of Tests at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests.html

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, 1974

Revision Information:

Date	Section Revised	Change
04/01/2012	Throughout	Initial Promulgation of Medicaid policy.
06/15/2012	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.
03/15/2017	Section 1.0	Added definitions for independent laboratory, outpatient hospital laboratory, referring laboratory and reference laboratory.

Date	Section Revised	Change
03/15/2017	Subsection 3.2.1	Clarified wording for specific covered criteria. Deleted related policies and place in box at beginning of policy on page 1. Added the following related policies to the list: 1E-5 Obstetrics 1E-7, Family Planning Services 1A-34, End Stage Renal Disease (ERSD) Services
03/15/2017	Subsection 4.2.1	Deleted the following: b. Contact local child support enforcement (IV-D) agency. c. Medicaid and NCHC does not cover
03/15/2017	Subsection 5.3	Deleted Entire Subsection: Testing Limitations a. Must be ordered by a licensed practitioner. b. Outpatient lab work or work done by independent laboratories is not counted toward the professional services visit limit.
03/15/2017	Subsection 5.4	Deleted outside and added independent
03/15/2017	Subsection 5.6	Clarified wording in this section about Pap Test
03/15/2017	Subsection 6.1	Added web address for the Division of Health Service Regulation Acute and Home Care Licensure and Certification and CLIA Program.
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.
01/03/2020	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."
01/03/2020	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".

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 and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

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.

Providers shall bill applicable Revenue Codes.

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

Inpatient, Outpatient, Clinic.

G. Co-payments

For Medicaid refer to Medicaid State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

For NCHC refer to NCHC State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>

Testing

- a. The performing physician or laboratory shall bill for performance of the test.
- b. Complete services are not reimbursed when professional or technical components have been paid in history for the same test on the same date of service.
- c. The *CPT Manual* assigns CPT codes to organ or disease oriented panels consisting of groups of specified tests. Components of panel codes cannot be reimbursed in addition to the panel code. When all the necessary tests ordered match a grouping, the appropriate panel must be billed. Tests that are unnecessary must not be added in order to match a panel.

Note: CMS mandates that the total amount paid for individual laboratory procedure codes not exceed the maximum fee allowed for lab panel fees. Reimbursement for automated lab tests is based on the total number of lab tests performed and not on the fee for each individual automated lab test. Our NC Medicaid rate setting determines the rates.

Venipuncture and Specimen Collection

- a. The only fee that a physician may bill, if the physician sends the lab work to an independent lab, is for venipuncture collection. One collection fee is allowed for each beneficiary, regardless of the number of specimens drawn. When a series of specimens is required to complete a single test, the series is treated as a single encounter.
- b. When the beneficiary is an inpatient in the hospital, venipuncture and specimen collection is included in the Diagnostic Related Grouping (DRG).
- c. Only one venipuncture collection charge is allowed for all specimens sent to one laboratory on a given occasion. If specimens are sent to two or more laboratories on a given occasion, additional handling charges may be allowed.

Rural Health Clinics/Federally Qualified Health Centers

Rural health clinic or the federally qualified health center (RHC/FQHC) providers shall bill laboratory services that are performed at the RHC or FQHC using their provider number. Laboratory services not rendered in the RHC or FQHC but sent to a referring laboratory must

be billed by the referring laboratory. The laboratory that performs the service shall meet CLIA certification requirements and bill for the service rendered.

Because there is a national cap on payment for laboratory services, the maximum allowable rate for laboratory services is established through the laboratory schedule. No additional reimbursement for laboratory services is provided through cost adjustments at the end of the year.

Refer to clinical coverage policy 1D-4, *Core Services Provided in Federally Qualified Health Centers and Rural Health Clinics*, at <https://medicaid.ncdhhs.gov/>.

Pap Test

- a. There is no separate fee for the collection of a Pap test. The collection of the Pap test is reimbursed as part of the office visit.
- b. Pap test codes can only be billed when a provider is CLIA certified.

Laboratory Pathology

Physician pathology services have a technical modifier, TC and professional modifier, 26, component. When physician pathology CPT codes are performed in a hospital setting, the physician shall bill only for the professional component by billing the correct CPT code with modifier 26. The hospital shall receive reimbursement for only the technical component.

When a physician pathology service is performed in an independent laboratory, the independent laboratory shall bill the complete procedure either by billing the professional component using modifier 26 plus the technical component, modifier TC, or by billing the complete procedure with no modifier. Reimbursement is the same for either billing option; neither can exceed the allowance for the complete procedure. Refer to the **Testing** section above.

No modifier denotes the billing of the complete procedure when the provider performs both the technical and professional components.

Modifier 26 is the professional component. The professional component involves the supervision and interpretation of the CPT procedure. The provider using modifier 26 must prepare a written report that includes findings, relevant clinical issues, and, if appropriate, comparative data.

Modifier TC is the technical component. The technical component charges are usually institutional charges such as equipment or cutting of slide.

When both a hospital and provider office bill for a laboratory pathology service, the hospital is reimbursed for the technical component of the test. The provider office may only be reimbursed for the interpretation of the report by billing for the professional component.

Laboratory services furnished in the hospital inpatient or furnished in the outpatient hospital laboratory are not reimbursable to physicians, unless the physician is listed as an independent pathologist (specialty 22) or independent lab (specialty 69).

Hospitals employing pathologists shall bill the professional component under the hospital's professional number.

Medicaid and NCHC reimburse laboratory services furnished by a pathologist to an individual inpatient only for these services, and if they meet the appropriate conditions:

- a. Anatomical pathology services.
- b. Consultative pathology services, if these conditions are met:
 1. Requested by the beneficiary's attending physician.
 2. Relate to a test result that lies outside the clinically significant normal or expected range in view of the condition of the beneficiary.
 3. Result in a written narrative report included in the beneficiary's medical record.
 4. Require the exercise of medical judgment by the consulting pathologist.