

**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.**

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**Related Clinical Coverage Policies**

Refer to <https://medicaid.ncdhhs.gov/> for the related coverage policies listed below:

1A-14, Surgery for Ambiguous Genitalia

1E-4, Fetal Surveillance

1E-7, Family Planning Services

For information on the Newborn Screening Program, which is not within the scope of this policy, refer to NC Division of Public Health, Women's and Children's Health Website at:

<https://medicaid.ncdhhs.gov/>.

## **1.0 Description of the Procedure, Product, or Service**

Genetic testing can provide information about a beneficiary's genes and chromosomes.

A genetic test involves an analysis of human chromosomes, deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or gene products to establish a diagnosis of a genetic condition.

A genetic test is a diagnostic test used to identify a single gene or genomic condition.

### **1.1 Definitions**

#### **Genetic Counselor**

Genetic counselors are health professionals with specialized education, training, and experience in medical genetics and counseling. They help people understand and adapt to the implications of genetic contributions to disease.

#### **Genetic Counseling**

Genetic counseling is a process of communication that allows beneficiaries and their families to make informed medical decisions. These services may include obtaining a structured family medical and genetic history, constructing a multiple-generation genetic pedigree, performing an analysis of available medical information for genetic risk assessment, and counseling the beneficiary and family. This counseling includes natural history of disease, recurrence risk to family members, and availability of testing, screening and monitoring options. (Refer to **Subsection 6.2**)

A licensed physician may provide genetic counseling when there is no access to a fellowship-trained genetic subspecialty physician or a certified genetic counselor. The licensed physician shall discuss and document in the beneficiary's health record the following:

- a. likelihood of developing disease;
- b. impact of the disease;
- c. possibility of modification of either the impact or likelihood of disease; and
- d. anticipated future developments in diagnosis or treatment.

#### **Advanced Maternal Age**

The female beneficiary is age 35 years or older at the time of delivery.

## 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**  
NCHC beneficiaries who become pregnant shall be transitioned to another appropriate Medicaid eligibility category that includes pregnancy coverage, if eligible.

### 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

- a. Medicaid and NCHC shall cover genetic and cytogenetic testing for the diagnosis and treatment of a genetic condition when **all** of the following criteria are met:
  1. The beneficiary displays clinical features or is experiencing current signs and symptoms of a genetic condition;
  2. There is documented reasonable expectation that the beneficiary is at high-risk based on family history, personal history, or ethnicity;
  3. The test yields results that can be used to develop a clinical useful approach or course of treatment, or to cease unnecessary treatments;
  4. The results of the test allow providers to treat current symptoms affecting the beneficiary's health, or manage the treatable progress of an established disease;
  5. The ordering licensed physician shall obtain written informed consent (indicating understanding of the testing procedure, the benefits and limitations of the test, and the possible consequences of the test results) from the beneficiary, parent, legal guardian or authorized representative, prior to the genetic test;
  6. Test must be performed by a certified Clinical Laboratories Improvement Amendment (CLIA) laboratory;
  7. A clinically valid test, based on published peer-reviewed literature, is available for the suspected diagnosis;
  8. There is sufficient evidence in scientific literature to support the validity and predictive accuracy of the test; **and**
  9. There is genetic counseling both pre- and post-test. **Refer to Subsections 1.1 and 6.2.**
- b. Medicaid and NCHC shall cover genetic and cytogenetic testing for the diagnosis and treatment of genetic abnormalities or syndromes such as:
  1. multiple congenital anomalies;
  2. developmental delays; and

3. intellectual disabilities.
- c. Medicaid and NCHC shall cover cytogenetic testing for the diagnosis and treatment of the following neoplastic chromosome abnormalities or syndromes:
  1. Chronic Myelogenous Leukemia (CML);
  2. Acute Lymphoblastic(also known as lymphocytic) Leukemia (ALL);
  3. Acute Myeloid Leukemia (AML);
  4. Myelodysplastic syndromes (MDS);
  5. Lymphomas (solid tumors); and
  6. Multiple myeloma.
- d. Cystic fibrosis testing
  1. Testing for common variants of the cystic fibrosis gene is covered when a beneficiary has signs or symptoms of cystic fibrosis
  2. When the symptomatic beneficiary has a known familial variant, the test that is ordered should be for that specific variant.
  3. If no mutation is found when testing for common variants, and the beneficiary is symptomatic, full gene sequencing can be ordered after obtaining prior approval.
  4. After completing the full gene sequencing, if no mutation is found, testing may be done for duplication/deletion variants after obtaining prior approval

**Note:** Refer to Attachment A: Codes, for items 1-4 above

### 3.2.2 Medicaid Additional Criteria Covered

- a. In addition to the specific criteria covered in **Subsection 3.2.1 (a) (2-9)** of this policy, Medicaid shall cover non-invasive prenatal genetic testing for diagnosis of fetal abnormalities using cell-free DNA (refer to **Attachment A, Section C**) when a beneficiary with a high-risk singleton pregnancy has:
  1. advanced maternal age (refer to definition in **Subsection 1.1**);
  2. a targeted obstetrical ultrasound that detects a fetal structural abnormality;
  3. a history of a prior pregnancy with a trisomy; or
  4. parental balanced robertsonian translocation with increased risk of fetal trisomy 13 or 21.
- b. In addition to the specific criteria covered in **Subsection 3.2.1 (a) (2-9)** of this policy, Medicaid shall cover prenatal cytogenetic testing for diagnosis and treatment when the beneficiary has:
  1. advanced maternal age (refer to definition in **Subsection 1.1**);
  2. a targeted obstetrical ultrasound that detects a fetal structural abnormality
  3. a history of a prior pregnancy with a trisomy; or
  4. parental balanced robertsonian translocation with increased risk of fetal trisomy 13 or 21.

### 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 genetic testing when:

- a. there is no symptomatic evidence;
- b. the beneficiary does not meet the criteria listed in **Subsection 3.2**;
- c. the purpose is to identify a carrier for a genetic disorder;
- d. the screening is for the general population and ethnic groups;
- e. the test is being repeated after a negative test result; and
- f. a test is repeated when limited to once in a lifetime testing.

**Note:** Refer to **Attachment A, Section C, Code(s)** for codes that are limited to once in a lifetime.

#### 4.2.2 Medicaid Additional Criteria Not Covered

In addition to the specific criteria not covered in **Subsection 4.2.1** of this policy, Medicaid shall not cover genetic testing for:

- a. reproductive decision-making;
- b. male or female infertility;
- c. beneficiary family members;
- d. non-invasive prenatal testing by cell-free DNA, for low-risk pregnant women and for multiple gestations (except for the indications listed in **Subsection 3.2.2.a**);
- e. paternity testing;
- f. sex determination of the fetus;
- g. direct-to-consumer tests;

- h. molecular panels; and
- i. molecular profile tests.

#### **4.2.3 NCHC Additional Criteria Not Covered**

- a. In addition to the specific criteria not covered in **Subsection 4.2.1** of this policy, NCHC shall not cover services related to obstetrics, gynecology, complications of pregnancy, childbirth and the puerperium:
- b. 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 Genetic Testing, except as outlined in 3.2.1 (d), 3 and 4. Also, prior approval is required when exceeding the limitations found in **Attachment A, Section C**. Provider must follow Prior Approval requirements found in **Subsection 5.2.1**.

### **5.2 Prior Approval Requirements**

#### **5.2.1 General**

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

- a. the prior approval request; and
- b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

#### **5.2.2 Specific**

None Apply.

### **5.3 Additional Limitations or Requirements**

#### **5.3.1 Testing Limitations**

Refer to **Attachment A, Section C**, for testing limitations for CPT codes covered in this policy.

#### **5.3.2 Documentation Requirements**

When the provider requests additional units for the CPT Codes found in **Attachment A, Section C**, then, in addition to the prior approval requirements

found in **Subsection 5.2.1**, the following supporting documentation is required to justify the request:

- a. The reason for the test(s);
- b. Previous related lab results;
- c. How the test results contribute to improved health outcomes, and
- d. How the test results alter the beneficiary's treatment and management.

## **6.0 Providers 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.

### **6.1 Provider Qualifications and Occupational Licensing Entity Regulations**

None Apply.

### **6.2 Provider Certifications**

Genetic counseling is provided "incident to" the services of a physician. Genetic counseling must be provided by a genetic counselor that is certified by the American Board of Genetic Counseling or has an Active Candidate Status. A genetic counselor shall be employed by or under contract to hospitals or other entities that employ licensed physicians. Licensed physicians shall be responsible for providing on-site clinical supervision and be directly involved in the care of an NC Medicaid or NCHC beneficiary for whom the counseling service is billed.

Clinical laboratory services must be rendered only by medical care entities that are issued certifications that are in compliance with the Clinical Laboratories Improvement Amendment (CLIA) [Public Law 100-578, amended §353 of the Public Health Service Act (PHSA)].

## **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 and History

**Original Effective Date:** November 1, 1987

### History

| Date       | Section Revised                       | Change   |
|------------|---------------------------------------|--|
| 10/01/2008 | All sections and attachment(s)        | Initial promulgation of current coverage   |
| 07/01/2010 | All sections and attachment(s)        | Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."  |
| 08/01/2011 | Sections 1.0, 3.0, 4.0, 5.0, 6.0, 7.0 | Updated standard DMA template language   |
| 08/01/2011 | Section 3.0                           | Revised wording to clarify criteria  |
| 08/01/2011 | Subsection 3.5                        | Added, "All recipients undergoing genetic testing for any reason shall have both pre-and post-test genetic counseling with a licensed or certified genetic counselor or qualified physician. Refer to <b>Subsection 1.4.</b> "   |
| 08/01/2011 | Subsection 5.3                        | Deleted 88264 from list in 5.3 e. Added 5.3.i CPT code 88264 is limited to 2 units per day. Deleted 88273 from list in 5.3h. Added 5.3.j CPT code 88273 is limited to 3 units per day.   |
| 08/01/2011 | Subsection 7.2                        | Deleted "Laboratories may not bill N.C. Medicaid for a test performed while a patient is in hospital inpatient status. Payment arrangements must be made between the laboratory and the hospital. Medicaid"  |
| 08/01/2011 | Subsection 7.3                        | Removed Records Retention :As a condition of participation, providers are required to keep records necessary to disclose the extent of services rendered to recipients and billed to the N. C. Medicaid program [Social Security Act 1902(a) and 42 CFR 431.107]. Records must be retained for a period of at least five years from the date of service, unless a longer retention period is required by applicable federal or state law, regulations, or agreements (10A NCAC 22F.0107). Copies of records must be furnished upon request. The Health Insurance Portability and Accountability Act (HIPAA) does not prohibit the release of records to Medicaid (45 CFR 164.502). |
| 08/01/2011 | Attachment A (E)                      | Changed 1½ hours to 90 minutes   |

| Date       | Section Revised                | Change   |
|------------|--------------------------------|--|
| 08/01/2011 | Attachment A (B)               | Deleted wording that “covered ICD-9 CM diagnosis codes are listed below:” Added wording that “the provider shall ensure that the recipient meets the criteria in section 3.0 of this policy. The ICD-9 CM codes include:” Added the following codes to the diagnosis code table: 279.2, 287.31, 287.32, 287.33, 348.30, 348.31, 348.39 and 630.1. Deleted inactive diagnosis codes 655.22, 655.24 and 743.60. Added <b>Note:</b> Providers are to use diagnoses code 631 through September 30, 2011 and use ICD-9 diagnosis code 631.0 effective October 1, 2011.  |
| 08/01/2011 | Attachment A (D)               | Deleted “(CPT 2008 codebook)”  |
| 08/01/2011 | Attachment A (G)               | Added Cytogenetic Studies to co-payments   |
| 02/01/2012 | Attachment A: C                | Added statement about Revenue Codes billing  |
| 02/01/2012 | Section 6.0                    | Deleted “Genetic counseling is provided incident to the services of a physician. Genetic counseling may be provided by board-certified or board-eligible genetic counselors employed by or under contract to hospitals or other entities that employ board-certified or board-eligible genetic or prenatal diagnostic specialists (MDs or Dos) who are also enrolled with N.C. Medicaid. The specialist shall be responsible for providing on-site clinical supervision and must be directly involved in the care of recipients for whom the counseling service is billed.” Added to 6.0 “Genetic counseling is provided incident to the services of a physician. Genetic counseling may be provided by a genetic counselor that is certified by the American Board of Genetic Counseling or has an Active Candidate Status. A genetic counselor shall be employed by or under contract to hospitals or other entities that employ licensed physicians who are also Medicaid-enrolled providers. Licensed physicians shall be responsible for providing on-site clinical supervision and must be directly involved in the care of NC Medicaid recipients for whom the counseling service is billed.” |
| 03/12/2012 | All sections and attachment(s) | Technical changes to merge Medicaid and NCHC current coverage into one policy.   |
| 02/01/2013 | Section 1.0                    | Deleted “by light microscopy.”   |
| 02/01/2013 | All sections and attachment(s) | Replaced “recipient” with “beneficiary.”   |
| 07/03/2013 | Subsection 5.3                 | Corrected reference from, “See Attachment A Section G” – to “See Attachment A Section H”   |
| 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.   |
| 01/01/2016 | All sections and Attachments   | Policy title changed from “Cytogenetic Studies” to “Genetic Testing”   |

| Date       | Section Revised              | Change   |
|------------|------------------------------|--|
| 01/01/2016 | All sections and Attachments | Reviewed policy grammar, readability, typographical accuracy, and format. Policy amended as needed to correct, without affecting coverage.   |
| 01/01/2016 | All sections and Attachments | Updated policy boilerplate language  |
| 01/01/2016 | Section 1.0                  | <p>Added: Refer to <a href="http://dma.ncdhhs.gov/">http://dma.ncdhhs.gov/</a> for the related coverage policies listed below:<br/>           1A-14, Surgery for Ambiguous Genitalia<br/>           1E-4, Fetal Surveillance<br/>           1E-7, Family Planning Services</p> <p>For information on the Newborn Screening Program, which is not within the scope of this policy, refer to NC Division of Public Health, Women’s and Children’s Health Website at: <a href="http://dma.ncdhhs.gov/">http://dma.ncdhhs.gov/</a></p>   |
| 01/01/2016 | Section 1.0                  | <p>Added: “Genetic testing can provide information about a beneficiary’s genes and chromosomes.</p> <p>A genetic test involves an analysis of human chromosomes, deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or gene products to establish a diagnosis of a genetic condition.</p> <p>A genetic test is a diagnostic test used to identify a single gene or genomic condition.”</p> <p>Deleted: “Cytogenetics is the study of a cell’s chromosomal composition. Cytogenetic testing involves the determination of chromosome number and structure including deletions and duplications; variations in either can produce numerous abnormalities.</p> <p>Fluorescent in situ hybridization (FISH) is the application of fluorescently labeled DNA molecules to metaphase chromosomes and interphase nuclei for the detection of chromosomal abnormalities and alterations. It is a rapid, reliable, and direct approach for diagnosis, prognosis, and management of hematological malignancies. FISH is a component of testing for some non-cancerous genetic conditions for example DiGeorge syndrome, William’s syndrome, or Angelman syndrome and is also used for preliminary diagnosis, prognosis, and management of pregnancies with indications for testing.”</p> |
| 01/01/2016 | Subsection 1.1               | Deleted definitions for Constitutional Chromosomal Abnormalities and Acquired Neoplastic Chromosomal Abnormalities. Added definition for Advanced Maternal Age.  |

| Date       | Section Revised    | Change  |
|------------|--------------------|---|
| 01/01/2016 | Subsection 1.1     | <p>Added under Genetic Counseling:<br/>A licensed physician may provide genetic counseling when there is no access to a fellowship-trained genetic subspecialty physician or a certified genetic counselor. The licensed physician shall discuss and document in the beneficiary's health record the following:</p> <ul style="list-style-type: none"> <li>a. likelihood of developing disease;</li> <li>b. impact of the disease;</li> <li>c. possibility of modification of either the impact or likelihood of disease; and</li> <li>d. anticipated future developments in diagnosis or treatment.</li> </ul> |
| 01/01/2016 | Subsection 1.1     | <p>Added:<br/><b>Advanced Maternal Age</b><br/>The female beneficiary is age 35 years or older at the time of delivery.</p>   |
| 01/01/2016 | Subsection 2.1.2.b | <p>Added: "NCHC beneficiaries who become pregnant shall be transitioned to another appropriate Medicaid eligibility category that includes pregnancy coverage, if eligible."</p>  |
| 01/01/2016 | Subsection 3.2     | <p>This entire Subsection was substantively revised (and numbered Subsection 3.2.1) to provide clarification of current coverage for Medicaid and NCHC. This information is in Subsection 3.2.1 Specific Criteria Covered by both Medicaid and NCHC</p>   |

| Date       | Section Revised  | Change   |
|------------|------------------|--|
| 01/01/2016 | Subsection 3.2.2 | <p>This Subsection was added</p> <p>“Medicaid Additional Criteria Covered</p> <p>3.2.2 Medicaid Additional Criteria Covered</p> <p>a. In addition to the specific criteria covered in Subsection 3.2.1 (a) (2-9) of this policy, Medicaid shall cover non-invasive prenatal genetic testing for diagnosis of fetal abnormalities using cell-free DNA (refer to Attachment A, Section C) when a beneficiary with a high-risk singleton pregnancy has:</p> <ol style="list-style-type: none"> <li>1. advanced maternal age (refer to definition in Subsection 1.1);</li> <li>2. a targeted obstetrical ultrasound that detects a fetal structural abnormality indicating an increased risk of aneuploidy;</li> <li>3. a history of a prior pregnancy with a trisomy;</li> <li>4. positive test result for aneuploidy; or</li> <li>5. parental balanced robertsonian translocation with increased risk of fetal trisomy 13 or 21.</li> </ol> <p>b. In addition to the specific criteria covered in Subsection 3.2.1 (a) (2-9) of this policy, Medicaid shall cover prenatal cytogenetic testing for diagnosis and treatment when the beneficiary has:</p> <ol style="list-style-type: none"> <li>1. advanced maternal age (refer to definition in Subsection 1.1); or</li> <li>2. a targeted obstetrical ultrasound that detects a fetal structural abnormality.</li> </ol> |

| Date       | Section Revised  | Change  |
|------------|------------------|---|
| 01/01/2016 | Subsection 4.2.1 | <p>Subsection “Specific Non-Covered Criteria” was renamed “Specific Criteria Not Covered by both Medicaid and NCHC” and renumbered to be Subsection 4.2.1. Wording of the Subsection was revised</p> <p>From:</p> <p>“Medicaid and NCHC do not cover and cytogenetic studies for general population screening when:</p> <ol style="list-style-type: none"> <li>a. there is no symptomatic evidence, or</li> <li>b. the beneficiary does not meet the medical necessity criteria listed in Section 3.0.</li> </ol> <p>Note: Cytogenetic studies performed primarily for family planning purposes are not covered.”</p> <p>To:</p> <p><b>4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC</b></p> <p>Medicaid and NCHC shall not cover genetic testing when:</p> <ol style="list-style-type: none"> <li>a. there is no symptomatic evidence;</li> <li>b. the beneficiary does not meet the criteria listed in Subsection 3.2;</li> <li>c. the purpose is to identify a carrier for a genetic disorder;</li> <li>d. the screening is for the general population and ethnic groups;</li> <li>e. the test is being repeated after a negative test result; and</li> <li>f. a test is repeated when limited to once in a lifetime testing.</li> </ol> <p><b>Note: Refer to Attachment A, Section C, Code(s) for codes that are limited to once in a lifetime.</b></p> |

| Date       | Section Revised  | Change   |
|------------|------------------|--|
| 01/01/2016 | Subsection 4.2.2 | <p>“Medicaid Non-Covered Criteria” renamed “Medicaid Additional Criteria Not Covered:”</p> <p>Deleted: “No additional non-covered criteria.”</p> <p>Added:</p> <p>In addition to the specific criteria not covered in Subsection 4.2.1 of this policy, Medicaid shall not cover genetic testing for:</p> <ul style="list-style-type: none"> <li>a. reproductive decision-making;</li> <li>b. male or female infertility;</li> <li>c. beneficiary family members;</li> <li>d. non-invasive prenatal testing by cell-free DNA for low-risk pregnant women and for multiple gestations (except for the indications listed in Subsection 3.2.2.a)</li> <li>e. paternity testing;</li> <li>f. sex determination of the fetus;</li> <li>g. direct-to-consumer tests;</li> <li>h. molecular panels; and</li> <li>i. molecular profile tests.</li> </ul> |
| 01/01/2016 | Subsection 4.2.3 | <p>NCHC Non-Covered Criteria” renamed “NCHC Additional Criteria Not Covered:”</p> <p>added item: a</p> <p>“a. In addition to the specific criteria not covered in Subsection 4.2.1 of this policy, NCHC shall not cover services related to obstetrics, gynecology, complications of pregnancy, childbirth and the puerperium:”</p>  |
| 01/01/2016 | Subsection 5.2   | <p>Deleted Entire Subsection: Provision of Service</p> <p>In this version of the Policy, Subsection 5.2 becomes Prior Approval Requirements</p>  |
| 01/01/2016 | Subsection 5.2.1 | <p>Added:</p> <p>“5.2.1 General</p> <p>The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:</p> <ul style="list-style-type: none"> <li>a. the prior approval request; and</li> <li>b. all health records and any other records that support the beneficiary has met the specific criteria in Subsection 3.2 of this policy.”</li> </ul>   |
| 01/01/2016 | Subsection 5.3   | <p>Renumbered to Subsection 5.3.1 “Testing Limitations”</p>  |

| Date       | Section Revised  | Change   |
|------------|------------------|--|
| 01/01/2016 | Subsection 5.3.2 | <p>Documentation Requirements</p> <p>When the provider requests additional units for the CPT Codes found in Attachment A, Section C, then, in addition to the prior approval requirements found in Subsection 5.2.1, the following supporting documentation is required to justify the request:</p> <ol style="list-style-type: none"> <li>a. The reason for the test(s);</li> <li>b. Previous related lab results;</li> <li>c. How the test results contribute to improved health outcomes, and</li> <li>d. How the test results alter the beneficiary's treatment and management.</li> </ol>   |
| 01/01/2016 | Subsection 5.4   | Deleted Entire Subsection: "Documentation Requirements"  |
| 01/01/2016 | Subsection 6.2   | <p>Added Heading "Provider Qualifications"</p> <p>Statement revised From:</p> <p>"Genetic counseling is provided incident to the services of a physician. Genetic counseling may be provided by a genetic counselor that is certified by the American Board of Genetic Counseling or has an Active Candidate Status. A genetic counselor shall be employed by or under contract to hospitals or other entities that employ licensed physicians who are also Medicaid-enrolled providers. Licensed physicians shall be responsible for providing on-site clinical supervision and must be directly involved in the care of NC Medicaid beneficiaries for whom the counseling service is billed."</p> <p>To:</p> <p>Genetic counseling is provided incident to the services of a physician. Genetic counseling must be provided by a genetic counselor that is certified by the American Board of Genetic Counseling or has an Active Candidate Status. A genetic counselor shall be employed by or under contract to hospitals or other entities that employ licensed physicians. Licensed physicians shall be responsible for providing on-site clinical supervision and be directly involved in the care of an NC Medicaid or NCHC beneficiary for whom the counseling service is billed.</p> |

| Date       | Section Revised | Change  |
|------------|-----------------|---|
| 01/01/2016 | Attachment A    | <p>Attachment A: C – Added Unit Limitations for CPT Codes<br/>CPT codes 88230, 88233, 88235, 88237, 88239, 88245, 88248, 88261, 88262, 88263, 88264, 88267 and 88269 are limited to 4 units within a 12 month period. CPT code 88235 is not covered under NCHC.</p> <p>CPT codes 88271 is limited to 41 units within a 12 month period.</p> <p>CPT codes 88272, 88273, 88274, 88283, 88285and 88289 are limited to 1 unit within a 12 month period.</p> <p>CPT code 88280 is limited to 2 units within a 12 month period.</p> <p>CPT code 88291 is limited to 25 units within a 12 month period.</p> <p>CPT code 96040 is limited to 3 units (1 unit =30 minutes) 90 minutes total. Refer to Subsection 3.2.1a.6.</p> <p>CPT codes 81228 and 81229 are limited to 1 unit per day.</p> <p>CPT code 81507 is limited to 3 units within a 12 month period</p> <p>CPT codes 81220, 81221, 81240, 81241, 81243, 81244, 81256, 81331 are limited to once in a lifetime.</p> <p>CPT codes 81222 and 81223 are limited to once in a lifetime, with PA</p> |
| 01/01/2016 | Attachment A    | Attachment A: C – Deleted ICD-9 Codes   |

| Date       | Section Revised                  | Change  |
|------------|----------------------------------|---|
| 01/01/2016 | Attachment A                     | Attachment A: H – Deleted:<br>Testing Limitations<br>a. CPT codes, 88245, 88248, 88261, 88262, 88263, 88267, 88269, 88283, 88289, and 88291 are limited to 1 unit each per day.<br>b. CPT codes 88230, 88233, and 88239 are limited to 2 units each per day.<br>c. CPT code 88271 is limited to 42 units per day.<br>d. CPT code 88280 is limited to 5 units per day.<br>e. CPT codes 88237 and 88285 are limited to 4 units each per day.<br>f. CPT code 88235 is limited to 3 units per conception. (NCHC exclusion see Attachment A Billing Code (s)).<br>g. CPT code 96040 is limited to 3 units (1 unit = 30 minutes) per day.<br>h. CPT codes 88272, 88274 and 88275 are limited to 25 units per day.<br>i. CPT code 88264 is limited to 2 units per day.<br>j. CPT code 88273 is limited to 3 units per day. |
| 01/01/2016 | Attachment A                     | The following wording and related table of ICD-9 codes removed: “Providers shall bill the ICD-9-CM diagnosis code(s) to the highest level of specificity that supports medical necessity. The provider shall ensure that the beneficiary meets the criteria in <b>Section 3.0</b> of this policy. The ICD-9 CM codes include:”  |
| 01/06/2016 | Subsection 5.1 and Attachment A  | Corrected minor typos in numbering of Subsections. No effect on coverage or scope of policy, so no change made to Amended Date.   |
| 06/01/2016 | Attachment A                     | Corrected minor typos in numbering of Subsection. No effect on coverage or scope of policy, so no change made to Amended Date.  |
| 06/15/2016 | Section 8.0                      | Notation for 10/1/2015 regarding ICD-10 update returned to the table. This was inadvertently dropped out during the policy revision process of 01/01/2016. No effect on coverage or scope of policy, so no change made to Amended Date.   |
| 01/01/2019 | Attachment A: Claims Information | Code(s)CPT code 81420 is limited to 3 units within a 12- month period.  |
| 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.   |

### 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)

**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 select 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), ICD-9-CM procedure codes, 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.

| CPT Code | Unit Limitations  |
|----------|---|
| 81220    | Once in a lifetime (Refer to Subsection 3.2.1.d.1)          |
| 81221    | Once in a lifetime (Refer to Subsection 3.2.1.d.2)          |
| 81222    | Once in a lifetime, with PA (Refer to Subsection 3.2.1.d.4) |
| 81223    | Once in a lifetime, with PA (Refer to Subsection 3.2.1.d.3) |
| 81228    | 1 unit per day  |
| 81229    | 1 unit per day  |
| 81240    | Once in a lifetime  |
| 81241    | Once in a lifetime  |
| 81243    | Once in a lifetime  |
| 81244    | Once in a lifetime  |
| 81256    | Once in a lifetime  |
| 81331    | Once in a lifetime  |
| 81507    | 3 units within a 12 month period                            |
| 81420    | 3 units within a 12 month period                            |
| 88230    | 4 units within a 12 month period                            |
| 88233    | 4 units within a 12 month period                            |

| CPT Code | Unit Limitations   |
|----------|--|
| 88235    | 4 units within a 12 month period<br>CPT code 88235 is not covered under NCHC:            |
| 88237    | 4 units within a 12 month period   |
| 88239    | 4 units within a 12 month period   |
| 88245    | 4 units within a 12 month period   |
| 88248    | 4 units within a 12 month period   |
| 88261    | 4 units within a 12 month period   |
| 88262    | 4 units within a 12 month period   |
| 88263    | 4 units within a 12 month period   |
| 88264    | 4 units within a 12 month period   |
| 88267    | 4 units within a 12 month period   |
| 88269    | 4 units within a 12 month period   |
| 88271    | 41 units within a 12 month period  |
| 88272    | 1 unit within a 12 month period  |
| 88273    | 1 unit within a 12 month period  |
| 88274    | 1 unit within a 12 month period  |
| 88275    | 1 unit within a 12 month period  |
| 88280    | 2 units within a 12 month period   |
| 88283    | 1 unit within a 12 month period  |
| 88285    | 1 unit within a 12 month period  |
| 88289    | 1 unit within a 12 month period  |
| 88291    | 25 units within a 12 month period  |
| 96040    | 3 units (1 unit = 30 minutes) 90 minutes total: Refer to <b>Subsection 3.2.1 (a) (9)</b> |

**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.

**CPT Code Update:** The provider shall refer to the annual January CPT Code Update Medicaid Bulletin Article on NC Medicaid’s website assessed at <https://medicaid.ncdhhs.gov/> for CPT codes covered, not covered and end-dated.

**D. Modifiers**

Provider(s) 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**

Inpatient, Outpatient, Office.

**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, see: <https://medicaid.ncdhhs.gov/>