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-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 is used to identify changes or abnormalities in chromosomes, genes, or proteins to confirm or rule out suspected genetic conditions. Testing samples include blood, amniotic fluid, or bodily tissues. 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. In general, three categories of genetic testing—cytogenetic, biochemical, and molecular—are available to detect abnormalities in chromosome structure, protein function, and DNA sequence, respectively.

1.1 Definitions

1.1.1 Amniocentesis

Amniocentesis (also referred to as an amniotic fluid test or, informally, an "amnio") is a medical procedure used primarily in prenatal diagnosis of chromosomal abnormalities and fetal infections. In this procedure, a small amount of amniotic fluid, which contains fetal cells, is sampled from the amniotic sac surrounding a developing fetus. The fetal DNA is then examined for genetic abnormalities.

The most common reason to have an amniocentesis performed is to determine whether a fetus has certain genetic disorders or a chromosomal abnormality, such as Down syndrome.

An amniocentesis is performed when a pregnant beneficiary is greater than 15 weeks gestation. Pregnant beneficiaries who choose to have this test are primarily those at increased risk for genetic and chromosomal problems.

1.1.2 Chorionic Villus Sampling (CVS)

Chorionic villus sampling is a type of prenatal diagnostic test to detect chromosomal problems that can result in genetic diseases and birth defects. It involves taking a small sample of part of the placenta (the chorionic villi) where it is attached to the wall of the uterus.

CVS can diagnose chromosomal abnormalities that cause conditions like Down syndrome, sickle cell anemia, cystic fibrosis, and Tay Sachs disease. It does not diagnose neural tube defects.

CVS is performed between the 10th and 13th week of pregnancy. It is reported to be 98 percent to 99 percent accurate in detecting genetic abnormalities.

1.1.3 Cytogenetics

Testing involves the examination of chromosomes to identify structural abnormalities.

1.1.4 Genetic Counselor

Genetic counselors are health professionals with specialized education, training, and experience in medical genetics and counseling. They are certified by the American Board of Genetic Counseling or have an Active Candidate Status for certification. They help people understand and adapt to the implications of genetic contributions to disease.

1.1.5 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 provider may provide genetic counseling when there is no access to a fellowship-trained genetic subspecialty physician or a certified genetic counselor. Similar to other genetic counselors, the licensed provider 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; and
e. Informed consent to testing was obtained after the beneficiary verbalized understanding of the testing procedure, the benefits and limitations of the test, and the possible consequences of the test results.

1.1.6 Nuchal Translucency (NT) Ultrasound

Nuchal Translucency (NT) ultrasound is a diagnostic prenatal screening assessment prescribed to detect chromosomal abnormalities associated with Down syndrome (trisomy 21), one of the most common genetic conditions affecting 1 in 700 U.S. babies each year. The screening also determines risk of trisomy 13 and trisomy 18 syndromes, rare and often fatal chromosomal abnormalities.

The NT ultrasound is done between 10 and 13 weeks, when nuchal translucency, the clear fluid located at the back of the fetal neck, can be measured. A higher

NT measurement during assessment increases the potential risk of fetal abnormalities being present.

1.1.7 Prenatal Testing

Prenatal testing consists of non-invasive prenatal screening (NIPS) and non-invasive prenatal testing (NIPT) and prenatal diagnosis, which are aspects of prenatal care that focus on detecting problems with the pregnancy as early as possible. These may be anatomic and physiologic problems with the health of the zygote, embryo, or fetus, either before gestation even starts or as early in gestation as practicable. Screening can detect problems such as neural tube defects, chromosome abnormalities, and gene mutations that would lead to genetic disorders and birth defects, such as spina bifida, cleft palate, Down syndrome, Tay–Sachs disease, sickle cell anemia, thalassemia, cystic fibrosis, muscular dystrophy, and fragile X syndrome. Some tests are designed to discover problems which primarily affect the health of the mother, such as PAPP-A to detect pre-eclampsia or glucose tolerance tests to diagnose gestational diabetes. Screening can also detect anatomical defects such as hydrocephalus, anencephaly, heart defects, and amniotic band syndrome.

1.1.8 Whole Exome Sequencing

An efficient strategy to selectively sequence the protein coding regions (exons) of a genome (the complete set of genes or genetic material present in a cell or organism), typically human, to discover rare or common variants associated with a genetic disorder or phenotype.

1.1.9 Spinal Muscular Atrophy

Spinal Muscular Atrophy (SMA) is a genetic neuromuscular disease characterized by muscle atrophy and weakness. The disease generally manifests early in life and is the leading genetic cause of death in infants and toddlers. SMA is caused by defects in the Survival Motor Neuron 1 (SMN1) gene that encodes the SMN protein. The SMN protein is critical to the health and survival of the nerve cells in the spinal cord responsible for muscle contraction (motor neurons).

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

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

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 genetic and cytogenetic testing for the diagnosis and treatment of a genetic condition when the following criteria are met:

1. The beneficiary displays clinical features or is experiencing current signs and symptoms of a genetic condition; **or**
2. There is documented reasonable expectation that the beneficiary is at high risk based on family history, personal history, or ethnicity; **or**
2. The test yields results that can be used to develop a clinically useful approach or course of treatment, or to cease unnecessary treatments; **and**
3. 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 or alter recommended screening or monitoring; **and**
4. The ordering licensed provider shall obtain 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; **and**
5. Test must be performed by a certified Clinical Laboratories Improvement Amendment (CLIA) laboratory; **and**

6. ~~A clinically valid test, based on published peer-reviewed literature, is available for the suspected diagnosis;~~ **and**
7. ~~The test is proven to be scientifically valid for the identification of the specific genetically-linked disease or clinical condition~~ **and**
8. ~~A certified genetic counselor or ordering provider shall counsel the beneficiary pre- and post-test. Refer to~~ **Subsections 1.1 and 6.2.**

~~b. Medicaid shall cover genetic and cytogenetic testing for the diagnosis and treatment of genetic abnormalities or syndromes such as:~~

~~1. Any congenital anomalies;~~
~~2. developmental delays; and~~
~~3. intellectual disabilities.~~

~~c. Medicaid 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. Medicaid shall cover genetic and cytogenetic testing for the diagnosis and treatment of cystic fibrosis (CF) when the following criteria are met:~~

~~1. The beneficiary has signs or symptoms of cystic fibrosis;~~
~~2. The beneficiary or guardian has undergone genetic counseling;~~
~~3. When the symptomatic beneficiary has a known familial variant, the test that is ordered should be for that specific variant;~~
~~4. If no mutation is found when testing for common variants~~ **and** ~~the beneficiary is symptomatic, full gene sequencing can be ordered;~~ **or**
~~5. After completing the full gene sequencing, if no mutation is found, testing may be done for duplication/deletion variants~~

~~e. Medicaid shall cover genetic and cytogenetic testing for the diagnosis and treatment of spinal muscular atrophy (SMA) when the following criteria are met:~~

~~1. The beneficiary has signs or symptoms of SMA;~~
~~2. The beneficiary or guardian has undergone genetic counseling;~~
~~3. When the symptomatic beneficiary has a known familial variant, the test that is ordered should be for that specific variant;~~
~~4. If no mutation is found when testing for common variants and the beneficiary is symptomatic, full gene sequencing can be ordered; or~~
~~5. After completing the full gene sequencing, if no mutation is found, testing may be done for duplication/deletion variants~~

~~f. Medicaid shall cover whole exome sequencing (WES) for the identification and treatment of ill-defined symptoms when the following criteria are met:~~

~~1. Phenotype is suspicious for a genetic diagnosis;~~

2. beneficiary has multiple major structural or functional congenital anomalies affecting unrelated organ systems, including metabolic disorders;
3. beneficiary has one major structural congenital anomaly and two or more minor structural anomalies; **or**
4. the beneficiary has at least 2 of the following:
   A. major structural congenital anomaly affecting a single organ system;
   B. neurological features including either significant intellectual disability, global developmental delay or autism;
   C. severe psychological or psychiatric disturbance or severe neuropsychiatric condition;
   D. symptoms of a complex neurodevelopmental disorder;
   E. family history strongly implicating a genetic etiology; **or**
   F. period of unexplained developmental regression unrelated to autism or epilepsy; **and**
5. The beneficiary is evaluated and counseled by a certified geneticist or provider with genetic counseling experience prior to the test being ordered and when the results are reviewed;
6. Test ordered will be used to guide treatment; **and**
7. The beneficiary is age 21 or younger.

3.2.2 Medicaid Additional Criteria Covered

In addition to the specific criteria covered in **Subsection 3.2.1** of this policy, Medicaid shall cover:

a. screening (serum screening with or without nuchal translucency ultrasound or cell-free DNA screening) and diagnostic testing (CVS or amniocentesis) for chromosomal abnormalities after counseling the beneficiary shall be offered to all beneficiaries early in pregnancy regardless of maternal age or baseline risk.

b. Medicaid shall cover carrier testing for cystic fibrosis (CF) when the beneficiary meets any of the criteria below:
   1. Beneficiary is pregnant or considering pregnancy;
   2. Beneficiary has a biological parent with CF or both biological parents are CF carrier status;
   3. The beneficiary has a family history or first-degree relative with CF; **or**
   4. Echogenic bowel has been identified on fetal ultrasound; **and**
   5. After genetic counseling has been provided, informed consent is obtained prior to, and beneficiary agrees to voluntary carrier testing

c. Medicaid shall cover carrier testing for spinal muscular atrophy (SMA) when the beneficiary meets the criteria below:
   1. Beneficiary is pregnant or considering pregnancy and has not previously been tested for SMA;
   2. After genetic counseling has been provided, informed consent is obtained prior to, and beneficiary agrees to voluntary carrier testing.

d. Medicaid shall cover carrier testing for Ashkenazi Jewish associated disorders (e.g., Bloom syndrome, Canavan disease, cystic fibrosis, familial

dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease) when the beneficiary meets the criteria below:

1. At least one partner is Ashkenazi Jewish **or** at least one partner is a known carrier of an Ashkenazi Jewish associated disorder;
2. History of a previous child born with an Ashkenazi Jewish associated disorder; **or**
3. One or both partners have a first or second-degree relative affected with an Ashkenazi Jewish associated disorder; **and**
4. Test will guide plan of care for current and future pregnancies.

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 shall not cover genetic testing when:

a. the beneficiary does not meet the criteria listed in **Subsection 3.2;**
b. the screening is for the general population;
c. the test is being repeated after a negative test result; and
d. 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's family members;
d. Cell-free DNA based screening in twin pregnancy in the setting of fetal demise, vanishing twin, or one or more anomaly detected in one or both twins.

e. NIPS/NIPT following a CVS or amniocentesis test that was able to yield results;
f. paternity testing;
g. sex determination of the fetus;
h. direct-to-consumer tests

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 shall not require prior approval for Genetic Testing, except as when exceeding the limitations found in **Attachment A, Section C**. Providers 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 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 must be provided by a medical provider or 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 beneficiary for whom the counseling service is billed. The services of the Genetic Counselor are billed by the supervising physician.

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 provider. Refer to **Subsection 1.4**."
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 **Note:** 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	Added: Refer to http://dma.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: http://dma.ncdhhs.gov/
01/01/2016	Section 1.0	Added: "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." 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. 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."
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	Added under Genetic Counseling: A licensed provider may provide genetic counseling when there is no access to a fellowship-trained genetic subspecialty physician or a certified genetic counselor. The licensed provider 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.
01/01/2016	Subsection 1.1	Added: **Advanced Maternal Age** The female beneficiary is age 35 years or older at the time of delivery.
01/01/2016	Subsection 2.1.2.b	Added: "NCHC beneficiaries who become pregnant shall be transitioned to another appropriate Medicaid eligibility category that includes pregnancy coverage, if eligible."
01/01/2016	Subsection 3.2	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

Date	Section Revised	Change
01/01/2016	Subsection 3.2.2	This Subsection was added "Medicaid Additional Criteria Covered 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 indicating an increased risk of aneuploidy; 3. a history of a prior pregnancy with a trisomy; 4. positive test result for aneuploidy; or 5. 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); or 2. a targeted obstetrical ultrasound that detects a fetal structural abnormality.

Date	Section Revised	Change
01/01/2016	Subsection 4.2.1	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 From: "Medicaid and NCHC do not cover and cytogenetic studies for general population screening when: a. there is no symptomatic evidence, or b. the beneficiary does not meet the medical necessity criteria listed in Section 3.0. Note: Cytogenetic studies performed primarily for family planning purposes are not covered." To: **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.

Date	Section Revised	Change
01/01/2016	Subsection 4.2.2	"Medicaid Non-Covered Criteria" renamed "Medicaid Additional Criteria Not Covered:" Deleted: "No additional non-covered criteria." Added: 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.
01/01/2016	Subsection 4.2.3	NCHC Non-Covered Criteria" renamed "NCHC Additional Criteria Not Covered:" added item: a "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:"
01/01/2016	Subsection 5.2	Deleted Entire Subsection: Provision of Service In this version of the Policy, Subsection 5.2 becomes Prior Approval Requirements
01/01/2016	Subsection 5.2.1	Added: "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."
01/01/2016	Subsection 5.3	Renumbered to Subsection 5.3.1 "Testing Limitations"

Date	Section Revised	Change
01/01/2016	Subsection 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.
01/01/2016	Subsection 5.4	Deleted Entire Subsection: "Documentation Requirements"
01/01/2016	Subsection 6.2	Added Heading "Provider Qualifications" Statement revised From: "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." To: 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.

Date	Section Revised	Change
01/01/2016	Attachment A	Attachment A: C – Added Unit Limitations for CPT Codes 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. CPT codes 88271 is limited to 41 units within a 12 month period. CPT codes 88272, 88273, 88274, 88283, 88285and 88289 are limited to 1 unit within a 12 month period. CPT code 88280 is limited to 2 units within a 12 month period. CPT code 88291 is limited to 25 units within a 12 month period. CPT code 96040 is limited to 3 units (1 unit =30 minutes) 90 minutes total. Refer to Subsection 3.2.1a.6. CPT codes 81228 and 81229 are limited to 1 unit per day. CPT code 81507 is limited to 3 units within a 12 month period CPT codes 81220, 81221, 81240, 81241, 81243, 81244, 81256, 81331 are limited to once in a lifetime. CPT codes 81222 and 81223 are limited to once in a lifetime, with PA
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: Testing Limitations a. CPT codes, 88245, 88248, 88261, 88262, 88263, 88267, 88269, 88283, 88289, and 88291 are limited to 1 unit each per day. b. CPT codes 88230, 88233, and 88239 are limited to 2 units each per day. c. CPT code 88271 is limited to 42 units per day. d. CPT code 88280 is limited to 5 units per day. e. CPT codes 88237 and 88285 are limited to 4 units each per day. f. CPT code 88235 is limited to 3 units per conception. (NCHC exclusion see Attachment A Billing Code (s). g. CPT code 96040 is limited to 3 units (1 unit = 30 minutes) per day. h. CPT codes 88272, 88274 and 88275 are limited to 25 units per day. i. CPT code 88264 is limited to 2 units per day. 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 **Section 3.0** 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.

Date	Section Revised	Change
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".
04/01/2023	Section 1.0, Description	Reworded for clarity and added information about the categories of genetic testing
04/01/2023	Section 1.1, Definitions	Added definitions for amniocentesis, chorionic villus sampling, cytogenetics, nuchal translucency ultrasound, prenatal testing, whole exome sequencing, spinal muscular atrophy and added certification status to genetic counselor definition. Added informed consent to genetic counseling. Advanced maternal age definition deleted
04/01/2023	Section 3.2.1(a)	reworded 3.2.1(a) number 8 and 9 for clarity; clarified a beneficiary only needs to meet ONE of criteria 1-3 but the test needs to meet all criteria 4-9
04/01/2023	Section 3.2.1(b)	Changed the word "multiple" to "any" congenital anomalies
04/01/2023	Section 3.2.1	Added letter "d" for genetic and cytogenic testing for CF and letter "e" for SMA and "f" for WES sequencing
04/01/2023	Section 3.2.2	Letters (a) and (b) combined and rewritten to meet current standards. Added letter "b" for CF carrier testing and letter "c" for SMA carrier testing; added letter "d" for Ashkenazi Jewish associated disorder carrier testing CF carrier testing, "c" and "e" combined
04/01/2023	Section 4.2.1	Removed letter (b) "the purpose to identify a carrier for a genetic disorder"
04/01/2023	Section 4.2.1(c)	Removed "ethnic group"
04/01/2023	Section 4.2.2	Added "Cell-free DNA based screening in twin pregnancy in the setting of fetal demise, vanishing twin, or one or more anomaly detected in one or both twins" and "NIPS/NIPT following a CVS or amniocentesis test that was able to yield results" Removed "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**)"
04/01/2023	4.2.2 (h),(i)	Removed molecular panels and molecular profiles
04/01/2023	Attachment A	CPT Codes added: 81224, 81443, 81329, 81336, 81337, 81415 Each with Unit Limitation: Once in a lifetime
04/01/2023	Throughout	Changed the term pregnant woman to pregnant beneficiary
4/15/2023	All Sections and Attachment(s)	Updated policy template language due to North Carolina Health Choice Program's move to Medicaid.

	All Sections and Attachments	Policy terminated and absorbed into new policies titled Genetic Testing – Diagnosis and Treatment, Genetic Testing – Carrier and Prenatal, and Genetic Testing – Next Generation Sequencing (NGS).

~~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-04/837I 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 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.~~

~~The following is a list of CPT codes for the labs that are covered under this policy along with their limitations.~~

~~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)~~
~~81224~~	~~Once in a lifetime~~
~~81443~~	~~Once in a lifetime~~

CPT Code	Unit Limitations
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
81329	Once in a lifetime
81331	Once in a lifetime
81336	Once in a lifetime
81337	Once in a lifetime
81415	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
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 **Subsection 3.2.1 (a) (9)**

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, Laboratory

G. Co-payments

For Medicaid refer to 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, see: https://medicaid.ncdhhs.gov/