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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1.0 Description of the Procedure, Product, or Service

Carrier genetic screening is a type of genetic test carried out to detect a beneficiary who may be susceptible to producing offspring with inherited recessive single gene disorders. While carriers themselves are typically unaffected by the disease, they can transmit harmful genetic variations to their children. This screening can be conducted during the preconception or prenatal stages.

Prenatal genetic tests consist of **non-invasive prenatal testing** (cell-free DNA testing, nuchal translucency ultrasound), and **prenatal diagnostic testing** (amniocentesis, CVS), 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. A screening test 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 Pregnancy-Associated Plasma Protein A (PAPP-A) to predict pre-eclampsia or glucose tolerance tests to diagnose gestational diabetes. Screening tests can also detect anatomical defects such as hydrocephalus, anencephaly, heart defects, and amniotic band syndrome.

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 abnormalities 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, such as spina bifida. 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 Close Relatives (First-, Second- and Third-Degree Relatives)

a. A **first-degree relative** is a close blood relative which includes the beneficiary's parents, full siblings, and children.
b. A **second-degree relative** is a blood relative which includes the beneficiary's grandparents, grandchildren, aunts, uncles, nephews, nieces and half-siblings.
c. A **third-degree relative** is a blood relative which includes the beneficiary's first-cousins, great-grandparents, and great-grandchildren on the same side of the family.

1.1.4 Expanded Carrier Screening Panels

Expanded carrier screening panels refer to comprehensive genetic tests that assess a beneficiary's potential to carry and pass on a wide range of genetic disorders or conditions, typically beyond the standard set of conditions in routine carrier screening. These panels examine a broader spectrum of genetic mutations, providing valuable information for family planning and reproductive decision-making.

1.1.5 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 a beneficiary understand and adapt to the implications of genetic contributions to disease.

1.1.6 Genetic Counseling

Genetic counseling is a process of communication that allows a beneficiary and their family to make informed medical decisions. These services 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;
d. Anticipated future developments in diagnosis or treatment; and
e. Informed consent to testing 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.

1.1.7 Nuchal Translucency (NT) Ultrasound

Nuchal Translucency (NT) ultrasound is a 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 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.

1.1.8 Prenatal Cell-Free DNA Screening

Prenatal cell-free DNA screening is a blood test administered to a pregnant beneficiary. Throughout pregnancy, a portion of the fetus's DNA is present in the mother's bloodstream. A cell-free DNA screening examines this DNA to determine if the baby has an increased risk of having chromosome related disorders.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

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

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*).
b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.1.2 Specific

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

a. <u>Medicaid</u>
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

Medicaid shall cover Genetic Testing for Carrier and Prenatal when the beneficiary meets the following specific criteria:

a. A certified genetic counselor or ordering provider shall evaluate and counsel the beneficiary pre- and post-test. Refer to **Subsections 1.1.6** and **6.2;**
b. After genetic counseling has been provided, informed consent is obtained prior to, and beneficiary agrees to testing;
c. The test must guide plan of care for current and future pregnancies;
d. The test must not be duplicative of another performed test;
e. The test must be performed by a certified Clinical Laboratories Improvement Amendment (CLIA) laboratory;
f. The test must be clinically valid, based on published peer-reviewed literature, and available for the suspected diagnosis; and
g. The test must be proven scientifically valid for the identification of a specific genetically linked disease or clinical condition.

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 Genetic Testing for Carrier when the beneficiary meets the following specific criteria:

a. Beneficiary is pregnant or considering pregnancy;
b. Beneficiary has not previously been tested for the same disorder; and
c. The test possesses sufficient sensitivity and specificity to inform clinical decision-making, and there is a clear understanding of residual risk.

Medicaid shall cover Genetic Testing for Prenatal Testing as described in **Section 1.0** for chromosomal abnormalities for a beneficiary early in pregnancy regardless of maternal age or baseline risk.

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 for Carrier or Prenatal for **ANY** of the following situations:

a. Reproductive decision-making if the criteria in **Section 3.2** are not met;
b. The same test is being repeated after a negative result;
c. Expanded carrier screening panels;
d. The test is repeated when limited to once in a lifetime testing;
e. Male or female infertility;
f. For beneficiary's close relatives (Refer to **Subsection 1.1.3**) other than the biological mother;
g. 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;
h. Cell-free DNA based screening in multifetal gestations (three or more fetuses);
i. Serum blood test or ultrasound following a CVS or amniocentesis that was able to yield results;
j. Paternity testing;
k. The test is solely for sex determination; or
l. The test is used to determine ancestry.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

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 for Carrier and Prenatal however, Medicaid shall require prior approval 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 provider shall submit all of the following supporting documentation 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 Provider(s) Eligible to Bill for the Procedure, Product, or Service

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

a. meet Medicaid qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

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: June 1, 2024

History:

Date	Section or Subsection Amended	Change
10/01/2024	All Sections and Attachment(s)	CCP 1S-4 terminated, and coverage absorbed into this new policy. Added additional CPT codes to coverage.

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

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Carrier Screening

CPT Code	Unit Limitations
81161	Once in a lifetime
81220	Once in a lifetime
81255	Once in a lifetime
81257	Once in a lifetime
81258	Once in a lifetime
81259	Once in a lifetime
81269	Once in a lifetime
81271	Once in a lifetime
81274	Once in a lifetime
81329	Once in a lifetime
81336	Once in a lifetime
81337	Once in a lifetime
81361	Once in a lifetime
81362	Once in a lifetime

81363	Once in a lifetime
81364	Once in a lifetime
81412	Once in a lifetime
81443	Once in a lifetime

Prenatal Testing

CPT Code	Unit Limitations
81228	Once per pregnancy
81229	Once per pregnancy
81349	Once per pregnancy
81420	Once per pregnancy
81422	Once per pregnancy
81507	Once per pregnancy
81508	Once per pregnancy
81509	Once per pregnancy
81510	Once per pregnancy
81511	Once per pregnancy
81512	Once per pregnancy
88230	Once per pregnancy
88233	Once per pregnancy
88237	Once per pregnancy
88239	Once per pregnancy
88245	Once per pregnancy
88248	Once per pregnancy
88249	Once per pregnancy
88261	Once per pregnancy
88262	Once per pregnancy
88263	Once per pregnancy
88264	Once per pregnancy
88267	Once per pregnancy
88269	Once per pregnancy
88271	Once per pregnancy
88272	Once per pregnancy
88273	Once per pregnancy
88274	Once per pregnancy
88275	Once per pregnancy
88280	Once per pregnancy
88283	Once per pregnancy
88285	Once per pregnancy
88289	Once per pregnancy
88291	Once per pregnancy
0209U	Once per pregnancy

Genetic Counseling

CPT Code	Unit Limitations
96040	3 units (1 unit = 30 minutes) 90 minutes total.

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

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

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

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

F. Place of Service

Inpatient, Outpatient, 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, refer to: https://medicaid.ncdhhs.gov//