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

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 BRCA-Related Cancers

Individuals with a genetic mutation in either BRCA1 or BRCA2 genes face an elevated susceptibility to certain types of cancer. In women, this includes an increased risk of breast, ovarian, and pancreatic cancers, while in men, it raises the likelihood of prostate, pancreatic, and breast cancers.

1.1.2 Breast Cancer

a. **Primary breast cancer** is the initial growth of malignant cells in the breast tissue, requiring early detection for effective treatment.
b. **Triple negative breast cancer** is an aggressive subtype without estrogen, progesterone, and HER2 receptors, requiring specialized treatment approaches like chemotherapy and immunotherapy.

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, great-grandchildren on the same side of the family.

1.1.4 Cytogenetic Testing

Cytogenetic testing involves the examination of cells obtained from various sources such as tissue, blood, bone marrow, or amniotic fluid. Its purpose is to identify alterations in chromosomes, including fractures, absences, rearrangements, or additional chromosomes. Specific changes in chromosomes can indicate the presence of genetic disorders, certain types of cancer, or other medical conditions. This type of analysis aids in the diagnosis of diseases, treatment planning, and assessing treatment efficacy.

1.1.5 Direct Antiglobulin Test (DAT)

The direct antiglobulin test (DAT) is a clinical laboratory test used to identify the presence of immunoglobulin or complement on the outer surface of red blood cells. Its purpose is to determine whether homolysis is caused by an immune or non-immune factor. It is important to interpret the results of the DAT alongside clinical and other laboratory information, as with any diagnostic test.

1.1.6 Family History

Family medical history is information about the health conditions and diseases that have affected close relatives, helping healthcare professionals assess the beneficiary's risk and plan personalized care.

1.1.7 Genetic Testing

Genetic testing involves analyzing the genetic code of an individual to identify variations, irregularities, or mutations that could potentially indicate a pathological condition.

1.1.8 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.

1.1.9 Genetic Counseling

Genetic counseling is a process of communication that allows beneficiaries and their families 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 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.

1.1.10 Gleason Score

The Gleason score is a grading system used to assess the aggressiveness of prostate cancer based on the appearance of cancer cells. It ranges from 2 to 10 and helps determine treatment options and prognosis.

1.1.11 Lynch Syndrome (LS) Related Cancers

LS-related cancers comprise colorectal, endometrial, gastric, ovarian, pancreas, urothelial, brain (typically glioblastoma), biliary tract, small intestinal cancers, as well as sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas as observed in Muir-Torre syndrome.

1.1.12 MMR Deficiency

Inadequate MMR (Mismatch Repair) function leads to an inability to rectify errors during DNA replication, consequently elevating the risk of cancer. Beneficiaries with LS inherit mutations in genes encoding for MMR proteins, which predisposes them to colorectal and other cancer types.

1.1.13 Personal History

Personal medical history is a summary of the beneficiary's past and current health information, aiding healthcare professionals in understanding their medical needs and providing appropriate care.

1.1.14 Red Blood Cell (RBC) Antigen Genotyping

RBC antigen genotyping testing proves valuable in determining allelic variants that predict red blood cell antigen phenotypes for beneficiaries who have recently received blood transfusions or have conflicting serological antibody results due to partial, variant, or weakly expressed antigens.

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 Diagnosis and Treatment when the beneficiary meets **ALL** of the following specific criteria:

a. Displays clinical features or is experiencing current signs and symptoms of a genetic condition; or there is documented reasonable expectation that the beneficiary is at high-risk based on family history, personal history, or ethnicity;
b. The test yields results that can be used to develop a clinically useful approach or course of treatment, or to cease unnecessary treatments;
c. 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;
d. 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;
e. A clinically valid test, based on published peer-reviewed medical literature, is available for the suspected diagnosis; and
f. The test is proven to be scientifically valid for the identification of a specific genetically linked disease or clinical condition.

3.2.1.1 Cystic Fibrosis (CF) and Spinal Muscular Atrophy (SMA)

Medicaid shall cover Genetic Testing for Diagnosis and Treatment of Cystic Fibrosis (CF) and Spinal Muscular Atrophy (SMA) when the criteria in **Subsection 3.2.1** and **ALL** of the following criteria are met:

a. The beneficiary has signs or symptoms of CF or SMA;

b. When the symptomatic beneficiary has a known familial variant, the test that is ordered for that specific variant;
c. If no mutation is found when testing for common variants and the beneficiary is symptomatic, full gene sequencing can be ordered; and
d. After completing the full gene sequencing, if no mutation is found, testing may be done for duplication and deletion variants.

3.2.1.2 BRCA-Related Cancers

Medicaid shall cover Genetic Testing for Diagnosis and Treatment of BRCA-Related Cancers (**Refer to Subsection 1.1.1**) when the criteria in **Subsection 3.2.1,** and **one or more** of the following conditions are met:

a. The beneficiary has a personal history of breast cancer with **one or more** of the following:
    1. Diagnosed age 45 years and younger;
    2. Diagnosed age 50 years and younger with **one or more** of the following:
        A. A previous primary breast cancer diagnosis;
        B. One or more close blood relatives with breast cancer at any age;
        C. One or more relatives with pancreatic cancer;
        D. One or more relatives with prostate cancer; or
        E. An unknown or limited family history;
    3. Diagnosed age less than or equal to 60 years with triple negative breast cancer;
    4. Diagnosed at any age with **one or more** of the following:
        A. Two(2) or more close blood relatives with breast cancer, pancreatic cancer or, prostate cancer at any age;
        B. One(1) or more close blood relative with breast cancer at age 50 years old or older;
        C. One(1) or more close blood relatives with ovarian carcinoma;
        D. Close male blood relative with breast cancer; or
        E. Ethnicity associated with higher mutation frequency such as Ashkenazi Jewish.

b. The beneficiary has a personal history of epithelial ovarian, fallopian tube or primary peritoneal cancer.

c. The beneficiary has a personal history of male breast cancer.

d. The beneficiary has a personal history of prostate cancer at any age and **one** of the following:
    1. One(1) or more close blood relatives with ovarian cancer at any age or breast cancer at age 50 years old and younger; or
    2. Two(2) relatives with breast, ovarian, or prostate cancer at any age.

e. The beneficiary has a personal history of metastatic prostate cancer (radiographic evidence).

f. The beneficiary has a personal history of pancreatic cancer at any age and **one of** the following:

1. One (1) or more close blood relatives with ovarian carcinoma at any age or breast cancer at fifty years old and older;
2. Two (2) relatives with breast, ovarian, or prostate cancer at any age; or
3. Ashkenazi Jewish heritage.

g. The beneficiary has a personal history of BRCA 1 and 2 mutation detected by tumor profiling on any tumor type in the absence of germline mutation analysis.

h. The beneficiary has a family history of known BRCA1 or BRCA2 gene mutation with **one of** the following:
   1. First or second-degree blood relative meeting any of the criteria in **Subsection 3.2.1.2**; or
   2. Third-degree relative with breast cancer or ovarian carcinoma and who has two (2) or more close blood relatives with breast cancer (at least one (1) before 50 years old) or ovarian carcinoma.

i. The beneficiary has a family history of two (2) or more primary breast cancers (asynchronous, synchronous, bilateral, or metacentric) in a single-family member.

j. The beneficiary has a family history of two (2) or more relatives on the same side of the family with breast, prostate, or pancreatic cancer.

k. The beneficiary has a family history of epithelial ovarian, fallopian tube or primary peritoneal cancer.

l. The beneficiary has a family history of male breast cancer.

m. The beneficiary has a family history of known mutation carriers.

3.2.1.3 Lynch Syndrome Related Cancers

Medicaid shall cover Genetic Testing for Diagnosis and Treatment of Lynch Syndrome related cancer(s) when the criteria in **Subsection 3.2.1** and **any one** of the following conditions are met:

a. For a beneficiary with a diagnosis of any Lynch Syndrome (LS) related cancer, multi-gene panel testing is covered when **one** of the following conditions is met:
   1. has a past personal medical history indicating a tumor with MMR deficiency, confirmed through polymerase chain reaction (PCR), next generation sequencing (NGS), immunohistochemistry (IHC) testing;
   2. received their diagnosis before reaching 50 years of age;
   3. experiences another LS-related cancer either simultaneously or at a different time, regardless of age;
   4. has at least one(1) close relative (first or second-degree) diagnosed with LS-related cancer before reaching the age of 50 years; or
   5. has a minimum of two (2) close relatives (first or second-degree) diagnosed with LS-related cancers, regardless of their age.

b. For a beneficiary aged 18 years and older with a documented family history of LS-related cancer, multi-gene panel testing is covered when the specific family mutation is unknown (due to unavailability of family member testing or testing results) and **one** of the following conditions is met:
   1. has at least one (1) first-degree relative diagnosed with LS-related cancer before the age of 50 years;
   2. has at least one (1) first-degree relative affected by LS-related cancer and concurrently experiences another LS-related cancer or develops it at a different time;
   3. has a minimum of two (2) first or second-degree relatives with LS-related cancer, and at least one of these relatives was diagnosed before the age of 50 years;
   4. has three (3) or more first or second-degree relatives with LS-related cancers, regardless of the age at diagnosis; or
   5. has a risk of having a pathogenic MMR gene variant is at least five (5) percent as determined by predictive models.

c. For beneficiaries aged 18 years and older in a family with a harmful familial Lynch Syndrome (LS) gene mutation, the following testing is covered:
   1. Testing that is restricted to the known familial mutation; or
   2. Full-scale genetic testing, which includes multi-gene panel testing, when the exact familial mutation remains unidentified.

3.2.1.4 Gene Mutation Testing for Cancer Susceptibility

Medicaid shall cover gene mutation testing for cancer susceptibility when the criteria in **Subsection 3.2.1** and **ALL** of the following criteria are met:

a. The genetic condition is linked to a potentially substantial risk of developing cancer;
b. Biochemical or other testing cannot identify the risk of the significant cancer linked to the genetic disorder;
c. Scientific literature has established a specific mutation, or set of mutations, as a dependable indicator of the risk of developing malignancy; and
d. The outcomes of the genetic test may influence the medical approach (such as surveillance, lifestyle) for the beneficiary receiving the test.

3.2.1.5 Duchenne Muscular Dystrophy (DMD) and Becker Muscular Dystrophy (BMD)

Medicaid shall cover Genetic Testing for Diagnosis and Treatment for Duchenne Muscular Dystrophy (DMD) and Becker Muscular Dystrophy (BMD) when the criteria in **Subsection 3.2.1** and **ALL** of the following criteria are met:

a. The beneficiary shows signs of DMD or BMD, such as gradually developing symmetric muscular weakness (with proximal muscles affected more than distal ones) and, in many cases, enlarged calf muscles. For those with DMD, reliance on a wheelchair usually

occurs before the age of 13, while for those with BMD, it typically happens after the age of 16.; and

b. The beneficiary's serum creatine kinase (CK) level is higher than normal.

3.2.1.6 Red Blood Cell Antigen Genotyping

Medicaid shall cover red cell genotyping for a beneficiary who meets **any one** of the following conditions:

a. diagnosed with sickle cell disease, thalassemia syndromes, hemoglobinopathies, or other medical conditions necessitating frequent blood transfusions;
b. experiencing post-transfusion hemolysis without detectable antibodies or identifiable alternate causes;
c. has undergone a blood transfusion within the past three (3) months and expect to undergo further blood transfusions;
d. has autoimmune hemolytic anemia**;**
e. has received multiple blood transfusions or who test positive for direct antiglobulin test (DAT+);
f. diagnosed with non-transfusion dependent thalassemia (NTDT) before receiving a transfusion in a pregnant beneficiary;
g. assist in the management of hemolytic disease of the fetus and newborn (HDFN); or
h. reconcile inconsistent serological antibody findings.

NOTE: Within **Section 3.2.1**, it is essential to emphasize that any mention of prostate cancer pertains exclusively to cases with a Gleason score of 7 or higher (refer to **Subsection 1.1.10**).

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 Diagnosis and Treatment when **ALL** of the following additional criteria are met:

a. A certified genetic counselor or ordering provider shall evaluate and counsel the beneficiary pre- and post-test. Refer to **Subsections 1.1.9** and **6.2;**
b. The test must not be duplicative of another performed test; and
c. The test must be performed by a certified Clinical Laboratories Improvement Amendment (CLIA) laboratory.

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 Diagnosis and Treatment for **any** of the following:

a. The beneficiary does not meet the criteria listed in **Subsection 3.2;**
b. The same test is being repeated after a negative result;
c. The test is repeated when limited to once in a lifetime testing;
d. The test is for beneficiary family members;
e. A cell-free DNA based screening is performed in twin pregnancy in the setting of fetal demise, vanishing twin, or one (1) or more anomaly detected in one (1) or both twins; or
f. The test is used to determine ancestry.

4.2.1.2 BRCA-Related Cancers

Medicaid shall not cover Genetic Testing for Diagnosis and Treatment for BRCA-Related Cancers for **any** of the following conditions:

a. The beneficiary does not meet the criteria in **Subsection 3.2.1.2;**
b. Repeat testing for BRCA1 or BRCA2 before using Lynparza; or
c. Testing of a beneficiary who is under 18 years of age.

4.2.1.3 Red Blood Cell Antigen Genotyping

Medicaid shall not cover red cell genotyping for **any** of the following conditions:

a. For beneficiaries who have undergone allogeneic hematopoietic stem cell transplants;
b. For diagnosing sickle cell disease;
c. For routine pre-transfusion testing; or
d. For routine solid organ transplant screening.

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 Diagnosis and Treatment; however, Medicaid shall require prior approval when exceeding the limitations found in **Attachment A, Section C.** The provider shall 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: October 1, 2024

History:

Date	Section or Subsection Amended	Change
10/01/2024	All Sections and Attachment(s)	CCP 1S-4 and 1S-5 terminated, and coverage absorbed into this new policy. New coverage criteria added for Lynch syndrome, cancer susceptibility, Duchenne Muscular Dystrophy (DMD) and Becker Muscular Dystrophy (BMD), and red blood cell (RBC) genotyping. New CPT codes added to coverage that fall under general criteria in Section 3.2.1(a).
10/01/2024	All Sections and Attachment(s)	Policy has an effective date of 06/01/2024 with an amended date of 10/01/2024.
02/01/2025	Attachment A, Section C	Codes updated per the annual CPT update. Effective date 01/01/2025

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.

BRCA-Related Cancers

CPT Code	Unit Limitations
	Single Gene
81162	Once in a lifetime
81163	Once in a lifetime
81164	Once in a lifetime
81165	Once in a lifetime
81166	Once in a lifetime
81167	Once in a lifetime
81212	Once in a lifetime
81215	Once in a lifetime
81216	Once in a lifetime
81217	Once in a lifetime
81309	Once in a lifetime
0172U	Once in a lifetime
0138U	Once in a lifetime

Gene Panels	
81432	Once in a lifetime
0102U	Once in a lifetime
0103U	Once in a lifetime
0129U	Once in a lifetime
0131U	Once in a lifetime
0132U	Once in a lifetime
0133U	Once in a lifetime
0134U	Once in a lifetime
0135U	Once in a lifetime

Cystic Fibrosis and Spinal Muscular Atrophy

CPT Code	Unit Limitations
81173	Once in a lifetime
81174	Once in a lifetime
81204	Once in a lifetime
81220	Once in a lifetime
81221	Once in a lifetime
81222	Once in a lifetime
81223	Once in a lifetime
81224	Once in a lifetime
81329	Once in a lifetime
81336	Once in a lifetime
81337	Once in a lifetime
0230U	Once in a lifetime

Duchenne Muscular Dystrophy (DMD) and Becker Muscular Dystrophy (BMD)

CPT Code	Unit Limitations
81161	Once in a lifetime

Hereditary Colorectal Cancers (such as Lynch Syndrome related cancers)

CPT Code	Unit Limitations
Single Gene	
81288	Once in a lifetime
81292	Once in a lifetime
81293	Once in a lifetime
81294	Once in a lifetime
81295	Once in a lifetime
81296	Once in a lifetime
81297	Once in a lifetime
81298	Once in a lifetime
81299	Once in a lifetime
81300	Once in a lifetime
81301	Once in a lifetime
81317	Once in a lifetime
81318	Once in a lifetime
81319	Once in a lifetime
81201	Once in a lifetime

81202	Once in a lifetime
81203	Once in a lifetime
0162U	Once in a lifetime
Gene Panels	
81435	Once in a lifetime
0101U	Once in a lifetime
0130U	Once in a lifetime
0238U	Once in a lifetime

Red Blood Cell Antigen Genotyping

CPT Code	Unit Limitations
81105	Once in a lifetime
81106	Once in a lifetime
81107	Once in a lifetime
81108	Once in a lifetime
81109	Once in a lifetime
81110	Once in a lifetime
81111	Once in a lifetime
81112	Once in a lifetime
0001U	Once in a lifetime

Other Gene Mutation Testing for Cancer Susceptibility

CPT Code	Unit Limitations
	Single Gene
81120	Once in a lifetime
81121	Once in a lifetime
81175	Once in a lifetime
81176	Once in a lifetime
81191	Once in a lifetime
81192	Once in a lifetime
81193	Once in a lifetime
81194	Once in a lifetime
81206	Once in a lifetime
81207	Once in a lifetime
81208	Once in a lifetime
81210	Once in a lifetime
81218	Once in a lifetime
81219	Once in a lifetime
81233	Once in a lifetime
81235	Once in a lifetime
81236	Once in a lifetime
81237	Once in a lifetime
81245	Once in a lifetime
81246	Once in a lifetime
81270	Once in a lifetime
81272	Once in a lifetime
81279	Once in a lifetime
81287	Once in a lifetime

81307	Once in a lifetime
81308	Once in a lifetime
81309	Once in a lifetime
81310	Once in a lifetime
81311	Once in a lifetime
81315	Once in a lifetime
81316	Once in a lifetime
81320	Once in a lifetime
81334	Once in a lifetime
81338	Once in a lifetime
81339	Once in a lifetime
81345	Once in a lifetime
81347	Once in a lifetime
81348	Once in a lifetime
81351	Once in a lifetime
81352	Once in a lifetime
81353	Once in a lifetime
81357	Once in a lifetime
81360	Once in a lifetime
Gene Panels	
81437	Once in a lifetime
0022U	Once in a lifetime

Other Single Gene Tests

CPT Code	Unit Limitations
81171	Once in a lifetime
81172	Once in a lifetime
81200	Once in a lifetime
81240	Once in a lifetime
81241	Once in a lifetime
81242	Once in a lifetime
81243	Once in a lifetime
81244	Once in a lifetime
81251	Once in a lifetime
81255	Once in a lifetime
81256	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
81291	Once in a lifetime
81302	Once in a lifetime
81303	Once in a lifetime
81304	Once in a lifetime
81331	Once in a lifetime

81332	Once in a lifetime
81361	Once in a lifetime
81362	Once in a lifetime
81363	Once in a lifetime
81364	Once in a lifetime
0234U	Once in a lifetime

Other Gene Panels

CPT Code	Unit Limitations
81412	Once in a lifetime
81441	Once in a lifetime
81443	Once in a lifetime

Genetic Counseling

CPT Code	Unit Limitations
96041	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//