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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:

1S-3, Laboratory Services

1S-4, Genetic Testing

1.0 Description of the Procedure, Product, or Service

The BRCA (BREast CAncer) gene test uses DNA(deoxyribonucleic acid) analysis to identify harmful changes (mutations) in either one of the two cancer susceptibility genes known as BRCA1 and 2. These mutations increase a beneficiary's susceptibility to certain types of cancer.

Harmful mutations in BRCA1 and BRCA2 increase the risk of several cancers in addition to breast and ovarian cancer. These include fallopian tube cancer and peritoneal cancer. Men with BRCA2 mutations and to a lesser extent BRCA1 mutations, are also at increased risk of breast cancer and prostate cancer. Both men and women with BRCA1 or BRCA2 mutations are at increased risk of pancreatic cancer.

1.1 Definitions

1.1.1 Genetic Counseling

Genetic counseling is the process of helping people understand and adapt to the medical, psychological and familial implications of genetic contributions to disease. This process integrates analysis of personal and family history, beneficiary and family education regarding disease process and treatment options, and counseling.

1.1.2 Licensed or Certified Genetic Counselor

Genetic counselors have advanced training in medical genetics and counseling to guide and support patients seeking more information about how inherited diseases and conditions might affect them or their families, and to interpret test results. Genetic counselors are certified through American Board of Genetic Counselors and can be physicians or advanced practice nurses with a certification in genetics.

1.1.3 First, Second and Third-Degree Relative

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

1.1.4 Gleason Score

A system of grading prostate cancer tissue based on how it looks under a microscope. Gleason scores range from 2 to 10 and indicate how likely it is that a

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tumor will spread. A low Gleason score means the cancer tissue is similar to normal prostate tissue and the tumor is less likely to spread; a high Gleason score means the cancer tissue is very different from normal and the tumor is more likely to spread.

1.1.5 Close Relative

Close blood relatives include first-, second- and third-degree relatives. Third-degree relatives must be on same side as family.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

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

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

2.1.2 Specific

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

a. Medicaid

An eligible Medicaid beneficiary shall be 18 years of age and older. A Medicaid beneficiary under 18 years of age is considered on a case-by-case basis under the EPSDT requirements.

b. NCHC

A NCHC beneficiary under the age of 18 is not eligible for BRCA 1 and 2 genetic testing.

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]

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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/>

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2.2.2 EPSDT does not apply to NCHC beneficiaries

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

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

3.0 When the Procedure, Product, or Service Is Covered

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

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

- a. Medicaid and NCHC shall cover BRCA 1 and 2 genetic testing when medically necessary for a beneficiary with a **personal history** of one or more of the following:
 1. Breast cancer with one or more of the following:
 - A. Diagnosed age 45 years or younger;
 - B. Diagnosed age 50 years or younger with one or more of the following:
 - i. An additional breast cancer primary;
 - ii. One or more close blood relatives with breast cancer at any age;
 - iii. One or more relatives with pancreatic cancer;
 - iv. One or more relatives with prostate cancer; **or**
 - v. An unknown or limited family history.
 2. Diagnosed age less than or equal to 60 years with triple negative breast cancer; **or**
 3. Diagnosed at any age with one or more of the following:
 - A. Two or more close blood relatives with breast cancer, pancreatic cancer or, prostate cancer (Gleason score 7 or greater) at any age;
 - B. One or more close blood relative with breast cancer at age 50 years old or older;
 - C. One or more close (first, second, or third degree on same side of family) blood relatives with ovarian carcinoma;
 - D. Close male blood relative with breast cancer; **or**

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- E. Ethnicity associated with higher mutation frequency such Ashkenazi Jewish.
- 4. Epithelial ovarian, fallopian tube or primary peritoneal cancer;
- 5. Male breast cancer;
- 6. Prostate cancer (Gleason score seven or greater) at any age **and** one of the following:
 - A. One or more close blood relatives with ovarian cancer at any age or breast cancer at age 50 years old or younger; or
 - B. Two relatives with breast, ovarian, or prostate cancer (Gleason score seven or greater) at any age;
- 7. Metastatic prostate cancer (radiographic evidence);
- 8. Pancreatic cancer at any age and one of the following:
 - A. One or more close blood relatives with ovarian carcinoma at any age or breast cancer at fifty years old or older;
 - B. two relatives with breast, ovarian, or prostate cancer (Gleason score seven or greater) at any age; or
 - C. Ashkenazi Jewish heritage; **or**
- 9. BRCA 1 and 2 mutation detected by tumor profiling on any tumor type in the absence of germline mutation analysis
- b. Medicaid and NCHC shall cover BRCA 1 and 2 genetic testing when medically necessary for a beneficiary with a **family history** of one or more of the following:
 - 1. Known deleterious BRCA1 or BRCA2 gene mutation with one of the following:
 - A. First or second-degree blood relative meeting ANY of the criteria in Section 3.2.1; **or**
 - B. Third-degree relative with breast cancer or ovarian carcinoma and who has two or more close blood relatives with breast cancer (at least one before 50 years old) or ovarian carcinoma;
 - 2. Two or more primary breast cancers (asynchronous, synchronous, bilateral, or metacentric) in a single-family member;
 - 3. Two or more relatives on the same side of the family with breast, prostate, or pancreatic cancer;
 - 4. Epithelial ovarian, fallopian tube or primary peritoneal cancer;
 - 5. Male breast cancer;
 - 6. Known mutation carrier;

3.2.2 Medicaid Additional Criteria Covered

None Apply

3.2.3 NCHC Additional Criteria Covered

None apply

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4.0 When the Procedure, Product, or Service Is Not Covered

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

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

Medicaid and NCHC shall not cover BRCA testing for ANY ONE of the following:

- a. Repeat testing for BRCA 1 and 2 prior to Lynparza therapy;
- b. A confirmed diagnosis of breast or ovarian carcinoma, but do not met the criteria in **Subsection 3.2.1**
- c. Genetic screening in the general population;
- d. BRCA 1 and BRCA 2 testing for a beneficiary without a personal or family history of breast, ovarian or other hereditary cancer;
- e. Testing of a beneficiary who is under 18 years of age.

4.2.2 Medicaid Additional Criteria Not Covered

None apply

4.2.3 NCHC Additional Criteria Not Covered

- a. In addition to the specific criteria not covered in **Subsection 4.2.1** of this policy, NCHC shall not cover
- b. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 1. No services for long-term care.
 2. No nonemergency medical transportation.
 3. No EPSDT.
 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

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5.0 Requirements for and Limitations on Coverage

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

5.1 Prior Approval

Medicaid and NCHC shall not require prior approval for BRCA1 and 2 genetic testing.

5.2 Prior Approval Requirements

5.2.1 General

None Apply

5.2.2 Specific

None Apply

5.3 Additional Limitations or Requirements

None Apply

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

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

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

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

Genetic Counselor Certification

North Carolina Medicaid and NCHC shall require certification in genetic counseling by the American Board of Genetic Counseling (ABGC).

6.2 Provider Certifications

Laboratories and other providers who are allowed to perform laboratory procedures under a valid Clinical Laboratory Amendment (CLIA) of 1998 and hold a certificate as (issued by the Centers for Medicare and Medicaid Services or its agent) are eligible to bill for the service.

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:

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- 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 01,2021

History:

Date	Section or Subsection Amended	Change
06/01/2021	All Sections and Attachment(s)	New policy documenting new coverage of BRCA genetic testing.

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Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

ICD-10-CM Code(s)
Z13.79
C25.0 - C25.9
C48.0 - C48.8
C50.011 - C50.929
C56.1 - C56.9
C57.00 - C57.02
D05.00 - D05.92
D24.1 - D24.9
N60.91 - N60.99
Z15.01
Z15.02
Z40.01
Z40.02
Z80.0
Z80.3
Z80.41
Z80.42
Z85.07

Note: Electronic health record and claim submission must contain a documented diagnosis of cancer or a family history of cancer.

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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.

CPT Code(s)
81162
81167
81212
81215
81217

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).

BRCA 1 and 2 genetic testing is limited to one (1) unit per lifetime.

F. Place of Service

Inpatient, Outpatient, Primary Private Residence, Genetic Center and Office.

G. Co-payments

For Medicaid refer to Medicaid State Plan:

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

For NCHC refer to NCHC State Plan:

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

H. Reimbursement

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

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