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1.0 Description of the Procedure, Product, or Service

Several genetic syndromes with an autosomal dominant pattern of inheritance that feature breast cancer have been identified. Of these, hereditary breast and ovarian cancer (HBOC) and some cases of hereditary site-specific breast cancer have in common causative mutations in BRCA genes. Families suspected of having HBOC syndrome are characterized by an increased susceptibility to breast cancer occurring at a young age, bilateral breast cancer, male breast cancer, and ovarian cancer at any age. Other cancers, such as prostate cancer, pancreatic cancer, gastrointestinal cancers, melanoma, laryngeal cancer, occur more frequently in HBOC families. Hereditary site-specific breast cancer families are characterized by early onset breast cancer with or without male cases, but without ovarian cancer. For this policy, both will be referred to collectively as hereditary breast and/or ovarian cancer.

Germline mutations in the BRCA1 and BRCA2 genes are responsible for the cancer susceptibility in the majority of HBOC families, especially if ovarian cancer or male breast cancer are features. However, in site-specific breast cancer, BRCA mutations are responsible for only a proportion of affected families, and research to date has not yet identified other moderate or high-penetrance gene mutations that account for disease in these families. BRCA gene mutations are inherited in an autosomal dominant fashion through either the maternal or paternal lineage. It is possible to test for abnormalities in BRCA1 and BRCA2 genes to identify the specific mutation in cancer cases, and to identify family members with increased cancer risk. Family members without existing cancer who are found to have BRCA mutations can consider preventive interventions for reducing risk and mortality.

1.1 Medical Term Definitions

- a. Autosomal dominant: requires only one affected parent to have the trait to pass it to offspring.
- b. Hereditary: the genetic transfer of a specific trait from parent to offspring.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are 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 recipient'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; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Genetic testing for breast and ovarian cancer is covered under the NC Health Choice Program when it is determined to be medically necessary because the following medical criteria are met:

- a. Genetic testing of cancer-affected recipients age 18 and older may be medically necessary under any of the following circumstances:
 1. Females who are affected with breast or ovarian cancer and are from families with a high risk of BRCA1 or BRCA2 mutation as defined in the Policy Guidelines;
 2. Females affected with early onset breast or ovarian cancer, or with breast or ovarian cancer and multiple primary cancers, or with bilateral breast or ovarian cancer, but who do not have a known family history of breast or ovarian cancer;
 3. Females affected with both breast and ovarian cancer;
 4. Males affected with breast cancer at any age; **OR**
 5. Those affected with breast or ovarian cancer and who are from an ethnic background, e.g., Ashkenazi Jewish descent, associated with deleterious founder mutations.
- b. Genetic testing of unaffected recipients age 18 and older may be considered medically necessary under any of the following circumstances:
 1. Unaffected recipients (male or female) from families with a known BRCA1 or BRCA2 mutation;
 2. Unaffected recipients from families with a high risk of BRCA1 or BRCA2 mutation based on a family history (See **Subsection 3.3**), where it is not possible to test an affected family member for a mutation; **OR**
 3. Unaffected recipients in populations at risk for specific founder mutations due to ethnic background, e.g., Ashkenazi Jewish descent, with one or more relatives with breast or ovarian cancer at any age.

3.3 Policy Guidelines

- a. The US Preventative Services Task Force (USPSTF) recommends the following in identifying families with a high risk for mutation in the BRCA1 and BRCA2 gene, both the maternal and paternal family histories are important and each lineage must be considered separately. For non-Ashkenazi Jewish women/adolescents, high risk includes the following:
 1. Three or more first or second degree relative with breast cancer regardless of age at diagnosis;

2. Two first-degree relatives with breast cancer, one of whom was diagnosed at age 50 years or younger;
 3. Combination of both breast and ovarian cancer among first- and second degree relatives;
 4. First degree relative with bilateral breast cancer;
 5. A combination of two or more first or second degree relatives with ovarian cancer regardless of age at diagnosis;
 6. A first or second degree relative with both breast and ovarian cancer at any age;
OR
 7. A history of breast cancer in a male relative.
- b. Genetic testing should be performed in a setting with adequately trained health care providers who can provide appropriate pre-and post-test counseling.
 - c. The facility should have a qualified laboratory to perform the test.
 - d. Families at high risk for harboring a BRCA1 or BRCA2 mutation are those in which the incidence of breast or ovarian cancer in first or second degree relatives suggests an autosomal dominant inheritance, i.e., about half the family members are affected.
 - e. The American College of Medical Genetics recommends that "early onset" breast or ovarian cancer be considered cancers that occur in recipients age 45 or younger.
 - f. The American Society of Clinical Oncology (ASCO) recommends that cancer predisposition testing be offered when 1) the person has a strong family history of cancer or very early age of onset of disease; 2) the test can be adequately interpreted; and 3) the results will influence the medical management of the recipient or family member.

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

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Genetic testing for breast and ovarian cancer is considered investigational and not covered for:

- a. either those affected recipients with breast or ovarian cancer or for unaffected recipients when the criteria in **Subsection 3.2** is not met; and
- b. recipients who are minors (under the age of 18 or younger) for BRCA 1 and BRCA 2 mutations.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for genetic testing for breast or ovarian cancer.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **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.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

HCPCS Codes				
S3818	S3819	S3820	S3822	S3823

CPT Codes				
83890	83891	83892	83893	83894
83896	83897	83898	83901	83902
83903	83904	83905	83906	83912

D. Modifiers

Providers 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

Outpatient Hospital and Office

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.