

UPMC Health Plan POLICY AND PROCEDURE MANUAL

POLICY NUMBER: MP.055
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SUBJECT: Molecular Susceptibility Testing for Breast Cancer and/or Ovarian Cancer
(BRCA Testing)
INDEX TITLE: Medical Management
ORIGINAL DATE: September 2006

This policy applies to the following lines of business: (Check those that apply.)

Commercial:					
HMO ()		POS ()		PPO ()	
Fully Insured ()		Self-funded/ASO ()		HSA ()	
Medicare Select ()		Medicare Supplement ()			
DPW-MA:					
Health Choices ()			Voluntary ()		All (X)
CMS-MA:					
OH ()		WV ()		PA ()	All (X) Other ()
HMO ()	PPO (X)	Specialty Needs Plan (X)		Part D ()	PFFS (X) All ()
PID-CHIP:					
Free ()			Sub ()		All (X)
APPLICABLE TO:					
Community Care ()			Work Partners ()		

I. POLICY

It is the policy of UPMC Health Plan to cover Molecular Susceptibility Testing for Breast Cancer and/or Ovarian Cancer (BRCA Testing) when it is medically necessary and according to the member's specific benefit plan.

UPMC Health Plan recognizes the evolution of genetic expression testing and the availability of genetic tests that identify the presence of gene alterations potentially associated with Breast and Ovarian Cancers. Testing to identify these genetic mutations is therefore appropriate and consistent with good medical practice and will be considered after review on an individual basis when performed for the specific indications detailed in this policy.

This policy on Molecular Susceptibility Testing for Breast Cancer and/or Ovarian Cancer (BRCA Testing) has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

All denials that are based on medical necessity and appropriateness as determined by a UPMC Health Plan Medical Director (Medical Director).

II. DEFINITIONS

Breast Cancer- refers to invasive breast cancer and/or ductal cancer in situ (DCIS).

Close Blood Relative-any First, Second or Third degree blood relative.

First Degree Relative- mother, sister, daughter, father, brother, son.

Second Degree Relative- aunt, niece, uncle, nephew, grandmother, grandfather, grandchild, half sibling.

Third Degree Relative- First cousins, great-grandparents

III. PURPOSE

The purpose of this policy is to define the appropriate indications for Molecular Susceptibility Testing for Breast Cancer and/or Ovarian Cancer (BRCA Testing).

IV. SCOPE

This policy applies to various UPMC Health Plan departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims Departments.

V. PROCEDURE

A. Medical Description

The discovery in 1994 of this breast-ovarian cancer susceptibility gene, known as BRCA1, led quickly to the development of tests for the presence of gene alterations potentially associated with breast cancer. At the same time, additional discoveries related to BRCA1, such as the discovery that a mutation known as 185delAG may be present in 1% of Jews of Ashkenazi descent, led to calls for large, population-based screening studies related to the gene.

Between 5% and 10% of women with breast cancer develop the disease due to the inheritance of a mutated copy of BRCA1 or BRCA2 genes. Families suspected of having hereditary breast and/or ovarian cancer are characterized by cancer occurring in premenopause, in multiple generations, often bilaterally and in a pattern suggesting an autosomal dominant pattern of inheritance. A positive test result indicates that a person has inherited a known BRCA1 or BRCA2 gene mutation, and has an increased risk of breast and/or ovarian cancer. Mutations of BRCA1 and BRCA2 are particularly common among members of Ashkenazi Jewish ancestry.

Genetic counseling prior to genetic testing is prudent, considering the impact of positive results on the member and the family.

B. Indications

BRCA testing is indicated in any **ONE** (1) of the following situations:

1. Family history with known BRCA1/BRCA2 mutation (male or female),
OR
2. Personal history of breast cancer (including invasive and ductal carcinoma insitu breast cancers) **and** at least one (1) of the following:
 - Diagnosed age \leq 45 years old, **or**
 - Diagnosed age \leq 50 years old **or** two (2) breast primaries (at any age) **and**:
 - 1 close blood relative with breast cancer \leq 50 years old, **or**
 - 1 close blood relative with epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer, **or**
 - Limited family history, such as fewer than 2- 1st or 2nd degree female relatives **or** female relatives surviving beyond 45 years in either lineage. When investigating limited family history, the maternal and paternal sides should be considered separately.
 - Diagnosed at any age **and** 2 close blood relatives with breast cancer **or** epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (at any age),
 - Close male blood relative with breast cancer,
 - Personal history of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer,
 - Personal background of ethnicity that is associated with higher mutational frequency (e.g. founder populations of Ashkenazi Jewish, Swedish, Icelandic, Hungarian or other),
Note: Testing for founder mutation(s), if available, should be performed first. Full sequencing may be considered if other HBOC criteria are met.
- OR**
3. Personal history of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer,
OR
4. Personal history of male breast cancer,
OR
5. Member with family history only **and** their close blood family relative meets any of the above criteria (1-4).
OR
6. Occasionally, blood or tissue samples from other non covered family members are required to provide the medical information necessary for the proper medical care of a member. Such testing for molecular-based testing for BRCA and other specific heritable disorders in non-members will be reviewed for **medical necessity** when **all** of the following conditions are met:
 - The information is needed to adequately assess risk in the member; **and**
 - The information will be used in the immediate care plan of the member; **and**
 - The non covered family member's benefit plan (if any) will not cover the test and the denial is based on specific plan exclusion.

C. Limitations

1. The following is considered **experimental and investigational** and therefore not covered:
 - BRCA testing to assess the risk of breast or prostate cancer in men without breast cancer,
 - BRCA testing for assessment of risk of cancers other than breast or ovarian cancers.
2. Genetic testing in minors for BRCA1 and BRCA2 mutations is considered **not medically necessary**, and is therefore, not a covered benefit.
3. BRCA is **not indicated** if testing is performed primarily for the medical management of other family members that are not covered by UPMC Health Plan.

D. Information Required for Review

In order to assess medical necessity for BRCA testing, adequate information must be furnished by the treating physician. Necessary information includes, but is not limited to, the following:

1. A letter of medical necessity, with the physician's evaluation of the member's condition, and detailed family history of Breast/Ovarian cancer among First and Second Degree Relatives (when applicable).

Additional information will be requested if necessary.

E. Review Process

1. The Medical Management staff assigned to review obtains the clinical information to determine if there is adequate clinical information. If the case does not meet the established criteria, it is referred to a Medical Director.
2. If referred, the UPMC Health Plan Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member's benefit plan.

F. Variations

N/A

G. References

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4. The American College of Medical Genetics, Policy Statement: Genetic Susceptibility to Breast and Ovarian Cancer: Assessment, Counseling and Testing Guidelines, 1999. www.acmg.net

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15. CDC MMWR Weekly, Genetic Testing for Breast and Ovarian Cancer Susceptibility: Evaluating Direct-to-Consumer Marketing --- Atlanta, Denver, Raleigh-Durham, and Seattle, 2003, July 16, 2004/ 53(27); 603-606. <http://www.cdc.gov/MMWR/preview/mmwrhtml/mm5327a1.htm>
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17. National Cancer Comprehensive Cancer Network , NCCN Clinical Practice Guidelines in Oncology™, Genetic /Familial High Risk Assessment: Breast and Ovarian Cancer, Hereditary Breast and/or Ovarian Cancer Testing Criteria, version 1 2009, 4/6/09. www.nccn.org

Disclaimer:

UPMC Health Plan medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of UPMC Health Plan and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

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