Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MP097

Section: Medical Benefit Policy

Subject: Genetic Testing for BRCA1 or BRCA2 for Breast or Ovarian Cancer

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I. Policy: Genetic Testing for BRCA1 or BRCA2 for Breast or Ovarian Cancer

II. Purpose/Objective:

To provide a policy of coverage regarding Genetic Testing for BRCA1 or BRCA2 for Breast or Ovarian Cancer

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional

capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

Triple negative breast cancer: a cancer negative for expression of estrogen and progesterone receptors, and for overexpression of HER2 receptors

DESCRIPTION: Approximately 5-10% of all breast and ovarian cancer can be attributed to a dominantly inherited susceptibility. Mutations in two genes, BRCA1 and BRCA2 are associated with much of the inherited forms of breast and ovarian cancer.

INDICATIONS:

The Plan considers molecular susceptibility testing for hereditary breast and ovarian cancer (HBOC) (BRCA1 and BRCA2 including sequencing and large rearrangement testing, aka BART testing) medically necessary in **ANY** of the following indications:

Members with a personal history of breast cancer and any of the following:

1. Breast cancer diagnosed at age 45 years or younger; or
2. Bilateral breast cancer or two breast primary breast cancers with the first breast cancer diagnosed at or prior to age 50 years; or
3. Breast cancer is diagnosed at age 50 years or younger with one of the following:
    a. At least one first, second, or third-degree relative with breast cancer at age 50 years or younger; or
    b. At least one first- second-, or third degree blood relative with epithelial ovarian cancer/fallopian tube/primary peritoneal cancer at any age
    c. At least one first- second-, or third degree blood relative with pancreatic cancer; or
    d. At least one first- second-, or third degree blood relative with prostate cancer (Gleason score ≥7;
4. Triple negative breast cancer diagnosed at age 60 years or younger
5. Breast cancer diagnosed at any age, with one of the following:
    a. two or more close first- or second-degree blood relatives with breast cancer and/or epithelial ovarian cancer/fallopian tube/primary peritoneal cancer at any age; or
    b. two breast primaries and at least one first, second, or third-degree blood relative with breast cancer at age 50 years or younger; or
    c. two breast primaries and at least one first, second, or third-degree blood relative with epithelial ovarian cancer/fallopian tube/primary peritoneal cancer at any age; or
    d. a first, second, or third-degree male blood relative with breast cancer; or
    e. a first, second, or third-degree blood relative with a known BRCA1 or BRCA2 mutation; or
    f. two or more close first- or second-degree blood relatives with pancreatic adenocarcinoma at any age
    g. ethnic descent associated with deleterious mutations (e.g. founder populations of Ashkenazi Jewish, Icelandic, Swedish, Hungarian, or Dutch)

Members with a personal history of epithelial ovarian cancer/fallopian tube/primary peritoneal cancer

Members with a personal history of pancreatic adenocarcinoma or prostate cancer (Gleason score >7) at any age with:

1. One or more close first- or second-degree blood relatives with breast cancer and/or epithelial ovarian cancer/fallopian tube/primary peritoneal cancer, or pancreatic or prostate cancer (Gleason score >7) at any age.

Members without a personal history of breast cancer, ovarian cancer/fallopian tube/primary peritoneal cancer, or pancreatic adenocarcinoma, but with a known mutation in a cancer susceptibility gene in the member, or within the family

Confirmatory testing and counseling for known variants (including 185delAG, 5382insC, or 6174delT).

Members without a personal history of breast cancer, ovarian cancer/fallopian tube/primary peritoneal cancer, or pancreatic adenocarcinoma, but with a family history of any of the following:

1. First or second-degree blood relative with a history of breast cancer diagnosed at 45 years or younger

2 First or second-degree blood relative with a history of breast cancer diagnosed at 50 years or younger with any of the following:
   - An additional primary including bilateral disease or two or more clearly separate ipsilateral primary tumors
   - One or more close blood relative with breast cancer at any age
   - An unknown or limited family history
3 First or second-degree blood relative diagnosed <60 y with a triple negative breast cancer
4 First or second-degree blood relative diagnosed at any age with any of the following:
   - One or more first, second, or third-degree blood relative with breast cancer diagnosed before 50 years of age
   - Two or more first, second, or third-degree blood relatives with breast cancer
   - Two or more first, second, or third-degree blood relatives with breast cancer primaries on the same side of family
   - One or more first, second, or third-degree blood relative with invasive ovarian cancer/fallopian tube or primary peritoneal cancer
   - Two or more first, second, or third-degree blood relatives with pancreatic cancer or aggressive prostate cancer (Gleason score >7) at any age
   - first, second, or third-degree male blood relative with breast cancer
   - An individual of ethnicity associated with higher mutation frequency (e.g. Ashkenazi Jewish) no additional family history may be required
5 First or second-degree blood relative with a history of invasive ovarian cancer (including fallopian tubes and primary peritoneal cancer
6 First or second-degree blood relative with a history of pancreatic cancer or prostate cancer (Gleason score >7) at any age with one or more first or second-degree blood relatives with breast and/ovarian cancer and /or pancreatic or prostate cancer (Gleason score >7)
7 Personal and/or family history of three or more of the following (especially if early onset):
   - Pancreatic cancer
   - Prostate cancer (i.e., Gleason score >7)
   - Brain tumors
   - Endometrial cancer
   - Thyroid cancer
   - Kidney cancer
   - Sarcoma
   - Adrenocortical carcinoma
   - Hamartomatous polyps of GI tract
   - Diffuse (multiple primaries) gastric cancer

Genetic testing is appropriate only when offered in a setting where a licensed or certified genetic counselor* or adequately trained health care professional is able to provide appropriate pre- and post-test genetic counseling, and medical necessity is supported by <u>ALL</u> of the following criteria:

1. The information is needed to adequately assess risk in the member; **and**
2. The information will be used in the immediate care plan of the member; **and**
3. Pedigree analysis establishes that the insured individual is in a high risk group for the disease; **or**
4. Clinical presentation of symptomology is evident and diagnosis cannot be established with conventional evaluation testing.

*A genetic counselor is considered by the Plan to be qualified if the following are met:

- M.S. or Ph.D. degree from a genetic counseling program approved/ certified by the American Board of Genetic Counseling or the American Board of Medical Genetics

or

- Board certified or board qualified/eligible in the orderly process of obtaining board certification by the American Board of Genetic Counseling or American Board of Medical Genetics

and

- Proof of current competence and demonstrated ability (minimum of two years recent and continual experience within the past three years).

EXCLUSIONS:

- Genetic testing for BRCA1 or BRCA2 mutations on those less than 18 years of age is considered **experimental, investigational, and unproven.**
- Testing of unaffected individuals with no significant family history of cancer or no known genetic mutations in the family is considered **not medically necessary**

- Genetic testing to assess the risk breast or prostate cancer in men without breast cancer is considered **experimental, investigational, and unproven.**
- The use of CHECK2 testing is considered **experimental, investigational, and unproven.**

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven services is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment.**

PROCESS:
The Plan will utilize available published, peer reviewed medical literature, independent technology assessment program reports and/or review by the Geisinger Clinic Technology Assessment Committee to evaluate the following criteria when assessing the validity and efficacy of a specific genetic test:

- The analytical power of a test determined by its sensitivity and specificity is established.
- There is evidence of defined outcome measures that permits conclusions concerning the effect on health outcomes.
- The net health outcomes benefit of the test as compared to established alternatives is evaluated if applicable.
- The availability of test to membership is evaluated.
- The appropriate governmental and/or professional regulatory body approval is established.
- The test result will influence the treatment or alter the management of the insured individual medical care plan
- The test result has the capability to confirm a diagnosis when conventional medical evaluation is equivocal.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Genetic Testing for BRCA1 or BRCA2 for Breast or Ovarian Cancer
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

81162 BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis

81211 BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants in BRCA1 (ie, exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon
81212 BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants
81213 BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants
81214 BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants (ie, exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)
81215 BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant
81216 BRCA2 (breast cancer 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81217 BRCA2 (breast cancer 2) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant
81432 Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 14 genes, including ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11, and TP53
81433 Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11

Medicare applicable ICD10 Codes:
C50.011 , C50.012 ,C50.021 , C50.022 , C50.111 , C50.112 , C50.121 , C50.122 , C50.211 , C50.212 , C50.221 , C50.222 , C50.311 , C50.312 , C50.321 , C50.322 ,C50.411 ,C50.412 ,C50.421 ,C50.422 , C50.511 , C50.512 , C50.521 , C50.522 , C50.611 , C50.612 , C50.621 , C50.622 , C50.811 , C50.812 , C50.821 , C50.822 , C50.911 ,C50.912 ,C50.921 C50.922 ,C56.1 ,C56.2 ,C57.01 ,C57.02 ,D05.01, D05.02 ,D05.11 , D05.12 , D05.81 , D05.82 , D05.91 , D05.92 , Z17.0 , Z17.1,C25.0 , C25.1 , C25.2 , C25.3 , C25.4 , C25.7 , C25.8 ,C25.9 , C61Z15.01 - Z15.09- Z80.0 , Z80.3 , Z80.41 , Z80.42 Z85.07 , Z85.3 , Z85.43 , Z85.46

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 9/25/98

Revised: 6/17/99; 6/27/03, 7/23/04; 6/20/05;6/06 (removed prior auth); 6/07 (revised criteria); 7/08; 7/09 (add'l exclusion); 12/09 (revised criteria); 12/10 (revised criteria); 6/11 (clarified criteria for males); 1/13 (added triple negative criteria); 7/13(removed BART testing indications) , 4/14(updated criteria); 4/16 (revised criteria); 3/17(revised criteria); 5/18 (added criteria related to known variants)

Reviewed: 4/15, 3/18