UTILIZATION MANAGEMENT POLICY

TITLE: GENETIC TESTING FOR SUSCEPTIBILITY TO HEREDITARY BREAST AND / OR OVARIAN CANCER

EFFECTIVE DATE: November 19, 2018

This policy was developed with input from specialists in oncology, hematology and cancer genetics and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE

To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of genetic testing for susceptibility to hereditary breast and ovarian cancer. The Benefit Considerations box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND

I. Definitions

A. **BRCA 1 and BRCA 2** (BReast CAncer) are genes that suppress tumor development in many areas throughout the body. A mutation in either of these genes may cause their tumor suppressing properties to malfunction and may be indicative of a predisposition for hereditary breast and ovarian cancer.

B. **BRACAnalysis® Rearrangement Test (BART)** is a molecular diagnostic test that detects rare, large rearrangements of deoxyribonucleic acid (DNA) in the BRCA 1 and BRCA 2 genes. It is intended for patients with a strong family history of breast and ovarian cancer. The test can be performed with blood drawn in the laboratory, doctor's office, hospital, or clinic and is referred to as reflex testing.

C. **Close blood relative** includes first, second, or third degree blood relatives (for this policy only). **First degree relative** is a relative with whom one half of an individual's genes are shared (i.e., parent, sibling, offspring). **Second degree relative** is a relative with whom one quarter of an individual's genes is shared (i.e., grandparent, grandchild, uncle, aunt, nephew, niece, half-sibling). **Third degree relatives** are defined as great-grandparents, great-aunts, great-uncles, great-grandchildren, and first cousins.

D. **Founder mutation**: A gene mutation observed in high frequency in a specific population (frequently referenced in the literature as "founder population") due to the presence of that gene mutation in a single ancestor or small number of ancestors.

E. A **genetic counselor** is a health professional with specialized training and clinical experience in the areas of medical genetics and counseling that has completed an accredited Masters or Doctorate Degree program and has been certified by the American Board of Genetic Counseling or the American Board of Medical Genetics. Genetic counselors work as members of a health care team providing information and support to individuals and/or families who have birth defects or genetic disorders or who may be at risk for a variety of inherited conditions. **Genetic counseling** services may be provided both before and after genetic testing and include, but are not limited to the following services:

1. The collection, documentation and interpretation of family and medical histories to assess the risk of
Genetic Testing for Susceptibility to Hereditary Breast and/or Ovarian Cancer
Medica Policy No. III-DIA.04

1. Prior authorization is required for genetic testing for susceptibility to hereditary breast and/or ovarian cancer. Please see the prior authorization list for product specific prior authorization requirements.

2. This utilization management policy does not apply to genetic testing for BRCA mutation (BRACAnalysis CDx diagnostic test) to assess potential response to Lynparza (olaparib) treatment for advanced ovarian cancer associated with germline BRCA mutations. See Medica utilization management policy, Olaparib (Lynparza®) and Medica coverage policy, Genetic and Pharmacogenetic Testing.

3. The Pre-Ovar KRAS Variant Test for susceptibility to ovarian cancer is investigative and therefore not covered.

4. Genetic testing is excluded and therefore not covered when performed in the absence of symptoms or high risk factors for a genetic disease or when knowledge of genetic status will not affect treatment decisions or screening for the disease (see Genetic Testing and Pharmacogenetic Testing coverage policy).

5. See also related Medica coverage policies: Genetic and Pharmacogenetic Testing and Genetic Testing and TP53 (p53) Testing for Li-Fraumeni Syndrome.

6. Coverage may vary according to the terms of the member’s plan document.

7. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s plan document.

8. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual’s case will be reviewed by the medical director or external reviewer. Practitioners are advised of the appeal process in their Medica Providers Administrative Manual.

**MEDICAL NECESSITY CRITERIA**

1. Genetic testing for susceptibility to hereditary breast and/or ovarian cancer, using single gene or multigene panels, in individuals NOT previously tested is considered medically necessary when documentation in the medical record indicates that all of the following criteria are met:

   A. The member is at least 18 years of age

   B. The individual to be tested has an increased likelihood of carrying a deleterious mutation in the *BRCA 1*,
BRCA 2, or other breast cancer susceptibility gene(s), (e.g., CHEK2, PALB2, ATM).

C. A board-certified and licensed (where required) genetic counselor, medical geneticist, or oncologist, independent of the laboratory performing the test, has reviewed and documented family history or pedigree, advised the patient of the potential benefits and harms of the testing and implications of the test results, and obtained written informed consent (genetic professionals are not excluded if they are employed by or contracted with a laboratory that is part of an integrated health system which routinely delivers health care services beyond just the laboratory test).

D. The test is ordered by a physician with expertise in the diagnosis and/or management of breast and ovarian cancer or board-certified and licensed (where required) genetic counselor independent of the laboratory performing the testing (genetic professionals are not excluded if they are employed by or contracted with a laboratory that is part of an integrated health system which routinely delivers health care services beyond just the laboratory test).

E. **One of the following** criteria are met:
   1. Requesting Individual with Personal History of Cancer
      Personal history of breast cancer and **one or more of the following**:
      a. Diagnosed with breast cancer at or before age 45
      b. Diagnosed with breast cancer at or before age 50 and **one of the following**:
         1) An additional breast cancer primary
         2) One or more close blood relative with breast cancer at any age
         3) One or more close relative with pancreatic cancer
         4) One or more relative with prostate cancer*
         5) An unknown or limited family history.
      c. Diagnosed at or before age 60 with triple negative breast cancer.
      d. Diagnosed at any age with **one of the following**:
         1) One or more close blood relatives with breast cancer, pancreatic cancer, or prostate cancer* at any age
         2) One or more close blood relatives with ovarian cancer
         3) A close male blood relative with breast cancer.
         **Note:** For an individual of ethnicity associated with a higher mutation frequency (e.g., Ashkenazi Jewish) no additional family history may be required.
      e. Personal history of ovarian cancer
      f. Personal history of male breast cancer
      g. Personal history of prostate cancer* at any age with 1 or more close blood relatives with ovarian cancer at any age or breast cancer at or before at 50, or 2 relatives with breast, pancreatic, or prostate cancer* at any age
      h. Personal history of pancreatic cancer at any age with 1 or more close blood relatives with ovarian cancer at any age or breast cancer at or before age 50 or two relatives with breast, pancreatic, or prostate cancer* at any age
      i. Personal history of pancreatic cancer and Ashkenazi Jewish ancestry
      j. BRCA 1/2 mutation detected by tumor profiling in the absence of germline mutation analysis.
   2. Requesting Individual with Family History of Known Genetic Mutation:
      Family history of a close relative with known positive BRCA1 or BRCA 2 mutation.
   3. Requesting Individual with Family History of Cancer and **one of the following**:
      a. First or second degree blood relative meeting any of the above criteria
      b. Third degree blood relative with breast cancer and/or ovarian cancer and at least two close blood relatives with breast cancer and/or ovarian cancer.

II. **Large genomic rearrangement testing** (e.g., BART) to identify individuals at risk for BRCA 1 and BRCA 2-related cancers (if the previous test did not include BART) is considered medically necessary when documentation in the medical record indicates that **all of the following** are met:
   A. The individual meets one or more of the criteria in Section I.
   B. Testing for BRCA 1 and BRCA 2 are negative.

*Gleason score ≥ 7*
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CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)
- For Medicare members, refer to the following, as applicable at: http://www.cms.hhs.gov/mcd/search.asp?

DOCUMENT HISTORY

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<tr>
<th>Original Effective Date</th>
<th>September 2009</th>
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<td>Administrative update(s)</td>
<td>05/01/2017</td>
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References:

Pre-9-2015 Medical Policy Committee (MPC):


Genetic Testing for Susceptibility to Hereditary Breast and/or Ovarian Cancer
Medica Policy No. III-DIA.04

09/2015 MPC
47. Isaacs C, Fletcher SW, Peshkin BN. Genetic testing for hereditary breast and ovarian cancer syndrome. In: UpToDate, Basow, DS (Ed), UpToDate, Waltham, MA, 2015.
52. Peshkin BN, Isaacs C. Genetic risk assessment for individuals at risk for hereditary breast and ovarian cancer syndrome. In: UpToDate, Basow, DS (Ed), UpToDate, Waltham, MA, 2015.
54. Peshkin BN, Isaacs C. Interpretation of uninformative BRCA1/BRCAl2 genetic testing results for hereditary breast and ovarian cancer. In: UpToDate, Basow, DS (Ed), UpToDate, Waltham, MA, 2015.

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75. Hayes, Inc. *Hayes GTE Synopsis: Breast Cancer Focus Panel (Fulgent Genetics).* April 2017. Lansdale, PA.

76. Hayes, Inc. *Hayes GTE Synopsis: Ovarian Cancer Focus Panel (Fulgent Genetics).* April 2017. Lansdale, PA.


**09/2018 MPC**


