Genetic Testing for Hereditary Breast and/or Ovarian Cancer

I. Policy

University Health Alliance (UHA) will reimburse for genetic testing for hereditary breast and/or ovarian cancer when they are determined to be medically necessary and when they meet the medical criteria guidelines (subject to limitations and exclusions) indicated below.

II. Criteria/Guidelines

A. Genetic testing for breast cancer susceptibility gene 1 (BRCA1) and breast cancer susceptibility gene 2 (BRCA2) mutations is considered medically necessary:

1. For any member from families with a known deleterious BRCA1 or BRCA2 mutation
2. For women with a personal history of breast cancer affected with any of the following:
   a. 45 years or younger, or premenopausal when diagnosed with breast cancer
   b. Diagnosed at 50 years or younger with:
      i. An additional breast cancer at any age; or
      ii. First, second, or third degree relative(s) with:
         • Breast cancer at any age; or
         • Pancreatic cancer; or
         • Prostate cancer (Gleason score >7 or metastatic); or
         • An unknown family history;
   c. 60 years or younger when diagnosed with triple negative breast cancer (estrogen receptor negative, progesterone receptor negative, human epidermal growth factor receptor 2 negative)
   d. Diagnosed at any age with:
      i. Personal or family history of two or more additional diagnoses of breast cancer; or
      ii. One or more first, second, or third degree relatives with breast cancer diagnosed at 50 years or younger; OR with diagnosis at any age of ovarian cancer, male breast cancer, metastatic prostate cancer, or pancreatic cancer.
   e. Ethnicity associated with deleterious founder mutations
3. Women with history of ovarian cancer at any age
4. Men affected with breast cancer at any age
5. Members with history of pancreatic cancer at any age AND first, second, or third degree relative(s) with any of the following:
   a. Breast cancer diagnosed at age 50 or younger
   b. Ovarian cancer
c. Two or more relatives with a diagnosis of breast, pancreatic, or prostate cancer at any age

d. Personal history of Ashkenazi Jewish ancestry

6. Men with history of high-grade prostate cancer (Gleason score ≥7 or metastatic) at any age with one or more first, second, or third degree relatives with ovarian carcinoma at any age or breast cancer diagnosed at 50 years or younger or two relatives with breast, pancreatic, or prostate cancer (Gleason score ≥7 or metastatic) at any age

7. BRCA1/2 pathogenic mutation detected by tumor profiling on any tumor type in the absence of germline mutation analysis

8. Genetic testing for BRCA1 and BRCA2 mutations of unaffected (no personal history of cancer) adults is covered only (subject to Limitations/Exclusions and Administrative Guidelines)

   a. After the genetic risk assessment (requiring prior authorization) and only when:
      
      i. The unaffected individuals (male or female) are from families with a known BRCA1 or BRCA2 mutation; OR
      
      ii. The unaffected individuals are from families with a high risk of BRCA1 or BRCA2 mutation based on a family history (see Policy Guidelines), and where it is not possible to test an affected family member for a mutation;
      
      iii. Third degree blood relative with breast cancer and/or ovarian carcinoma AND two or more first, second, or third degree relatives with breast cancer (one or more diagnosed at 50 years or younger) and/or ovarian carcinoma.
      
      iv. The genetic counselor concurs with the testing.

   b. Testing for genomic rearrangements of the BRCA1 and BRCA2 genes (BART testing) is covered (subject to Limitations/Exclusions and Administrative Guidelines) in patients who meet criteria for BRCA testing, whose testing for point mutations is negative.

   c. A member who does not meet the criteria above, but with one or more first or second degree relatives who meet the criteria, may benefit from testing. The significant limitations of interpreting test results for an unaffected individual should be discussed.

   Note: For familial assessment: first-, second-, and third-degree relatives on the same side of the family. The maternal and paternal sides should be considered independently. First-degree relatives refer to parents, full siblings or offspring. Second-degree relatives refer to grandparents, grandchildren, aunts, uncles, nephews, nieces or half-siblings. Third-degree relatives are defined as great-grandparents, great-aunts, great-uncles, first cousins.

B. Genetic Risk Assessments:

1. A genetic risk assessment is covered (subject to Limitations and Administrative Guidelines) in all individuals meeting criteria for genetic testing within this policy; or

   a. Have a first degree relative with early onset breast cancer (<45 years old or premenopausal); or

   b. Two affected first or second degree relatives with a BRCA-related cancer (breast, ovarian, fallopian tube or primary peritoneal cancer); or

   c. A first or second degree relative with a BRCA mutation.

2. For asymptomatic individuals, genetic counseling is covered (subject to Limitations and Administrative Guidelines) in unaffected (no personal history of cancer) women identified as high risk for a BRCA mutation by one of the screening tools recommended by the USPSTF
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Payment Policy

(Ontario Family History Assessment Tool (FHAT), Manchester Scoring System, Referral Screening Tool (RST), Pedigree Assessment Tool (PAT), FHS-7)

a. UHA requires pre-test genetic risk assessment (one visit with prior authorization) as a condition for approval of genetic testing of asymptomatic members.

3. Genetic risk assessments must also meet the following:

a. Services must be conducted by a properly certified/licensed and credentialed genetic specialist (i.e., board-certified medical geneticist (MD), board-certified clinical geneticist (PhD), board-certified genetic counselor (MS and/or CGC), or licensed advanced practice registered nurse in genetics (APRN);

b. Services must be conducted in a face-to-face consultation and a subsequent consultation letter or report must be submitted to the treating physician.

4. One risk assessment visit after genetic testing is covered for patients who qualified for predictive genetic testing under the following conditions:

a. Pre-test genetic risk assessment was conducted and covered as part of prior authorization for selected genetic tests as stated above;

b. The patient qualified and received the ordered genetic test according to the pre-test assessment;

c. A CLIA-certified laboratory submits a viable claim for the completed genetic test.

NOTE:

This UHA payment policy is a guide to coverage, the need for prior authorization and other administrative directives. It is not meant to provide instruction in the practice of medicine and it should not deter a provider from expressing his/her judgment.

Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or member individual benefit plans may apply, and this policy is not a guarantee of payment. UHA reserves the right to apply this payment policy to all UHA companies and subsidiaries.

UHA understands that opinions about and approaches to clinical problems may vary. Questions concerning medical necessity (see Hawaii Revised Statutes §432E-1.4) are welcome. A provider may request that UHA reconsider the application of the medical necessity criteria in light of any supporting documentation.

III. Limitations/Exclusions

A. An affected family member should be tested first whenever possible. Should a BRCA mutation be found in an affected family member, the DNA from the unaffected family member can be tested specifically using a tailored study for the same mutation of the affected family member without having to sequence the entire gene.

B. Genetic testing for unaffected individuals (of both the general population and of potentially high-risk ethnic populations) without a family history suggesting increased risk of BRCA mutation is not covered.

C. Genetic testing in minors for BRCA1 and BRCA2 mutations is not covered.

D. Genetic testing for BRCA1 and BRCA2 mutations is not covered for assessment of risk of other cancers including but not limited to pancreatic, prostate, and colon cancer.

E. Benefits are provided only for UHA members; benefits are not provided for family members without current UHA coverage.
F. Testing for CHEK2 genetic abnormalities (mutations, deletions, etc.) is not covered in affected and unaffected patients with breast cancer irrespective of family history as it has not been shown to improve health outcomes.

G. Laboratories that conduct genetic testing must be CLIA certified.

H. Repeat BRCA1 or BRCA2 mutation testing is not covered.

I. Testing for one or more single nucleotide polymorphisms (SNPs) to predict an individual’s risk of breast cancer is not covered as it has not been shown to improve health outcomes.

J. Providers are expected to follow National Comprehensive Cancer Network (for affected individuals) and the United States Preventive Services Task Force (for unaffected individuals) guidelines for testing strategies. Failure to follow guidelines may result in delay of processing claim for additional documentation requirements, or denial.

IV. Administrative Guidelines

A. Prior authorization is required for the following:
   1. Genetic risk assessments;
   2. Genetic testing for inherited BRCA1 or BRCA2 mutations.

B. To request prior authorization, please submit via UHA’s online portal. If a login has not been established, you may contact UHA at 808-532-4000 to establish one.

C. The information received should include the member’s family history and a brief summary as to why the genetic test is needed.

D. If prior authorization is not obtained, the member will not be held responsible for payment of denied services unless UHA’s Advance Financial Notice form is completed and signed. This form is available via UHA’s website: www.uhahealth.com.

E. Applicable Codes:

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<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>81162</td>
<td>BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis</td>
</tr>
<tr>
<td>81211</td>
<td>BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants in BRCA1 (i.e., exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)</td>
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<tr>
<td>81212</td>
<td>BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants</td>
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<tr>
<td>81213</td>
<td>BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants</td>
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<tr>
<td>81214</td>
<td>BRCA1 (breast cancer 1) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants (i.e., exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)</td>
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<td>81215</td>
<td>BRCA1 (breast cancer 1) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant</td>
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<tr>
<td>81216</td>
<td>BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis</td>
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<tr>
<td>81217</td>
<td>BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant</td>
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<tr>
<td>81432</td>
<td>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 10 genes, always including BRCA1, BRCA2, CDH1, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, and TP53</td>
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<tr>
<td>81433</td>
<td>Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include</td>
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analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11

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<tr>
<th>HCPCS Code</th>
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<tr>
<td>96040</td>
<td>Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family</td>
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<tr>
<th>HCPCS Code</th>
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<tr>
<td>S0265</td>
<td>Genetic counseling, under physician supervision, each 15 minutes</td>
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V. Policy History

Policy Number: MPP-0057-120301
Current Effective Date: 01/09/2019
Original Document Effective Date: 03/01/2012
Previous Revision Dates: 03/01/2012, 02/12/2018
PAC Approved Date: 03/01/2012