IHCP updates PA criteria for BRCA1 and BRCA2 genetic testing for breast and ovarian cancer

The Indiana Health Coverage Programs (IHCP) covers breast cancer susceptibility gene 1 (BRCA1) and breast cancer susceptibility gene 2 (BRCA2) genetic testing for members who meet the qualifying criteria. Prior authorization (PA) is required. Effective September 1, 2016, the PA criteria for coverage of BRCA genetic testing, when billed with the Current Procedural Terminology (CPT®) codes in Table 1, will be updated to include additional qualifying criteria regarding the member’s family history as well as the current criteria regarding the member’s personal history. These PA changes apply to dates of service (DOS) on or after September 1, 2016, for services delivered under the fee-for-service (FFS) delivery system.

Table 1 – BRCA genetic testing procedure codes for which PA criteria have been updated, effective September 1, 2016

<table>
<thead>
<tr>
<th>Procedure Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81162</td>
<td>BRCA1, BRCA2 (breast cancer 1 and 2) (eg, 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) (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 8-9 del 7.1kb)</td>
</tr>
<tr>
<td>81212</td>
<td>BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants</td>
</tr>
<tr>
<td>81213</td>
<td>BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants</td>
</tr>
<tr>
<td>81214</td>
<td>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)</td>
</tr>
<tr>
<td>81215</td>
<td>BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant</td>
</tr>
<tr>
<td>81216</td>
<td>BRCA2 (breast cancer 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis</td>
</tr>
<tr>
<td>81217</td>
<td>BRCA2 (breast cancer 2) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant</td>
</tr>
</tbody>
</table>

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Existing qualifying criteria regarding personal history

Individuals with a personal history of at least one of the following:

- Breast cancer diagnosis at age 45 or younger with or without family history
  OR
  Breast cancer diagnosis at age 50 or younger with one or more of the following:
  - Two breast primary cancers, with the first breast cancer diagnosis occurring at age 50 or younger
  - At least one close blood relative with breast cancer at age 50 or younger
  - At least one close blood relative with epithelial ovarian/fallopian tube/primary peritoneal cancer diagnosed at any age
  - A limited family history or adopted

- Diagnosed at age 60 or younger with triple-negative (ER-, PR-, HER2-) breast cancer

- Breast cancer diagnosed at any age with one or more of the following:
  - Two breast primary cancers in a single individual with at least one close blood relative with breast cancer diagnosed at age 50 or younger
  - Two breast primary cancers in a single individual with at least one close blood relative with epithelial ovarian/fallopian tube/primary peritoneal cancer diagnosed at any age
  - Two or more close blood relatives with breast and/or epithelial ovarian/fallopian tube/primary peritoneal cancer diagnosed at any age
  - Two or more close blood relatives with pancreatic cancer diagnosed at any age
  - Two or more close blood relatives with prostate cancer (Gleason score of 7 or greater) diagnosed at any age
  - Close male blood relative with breast cancer (first-degree or second-degree blood relative allowable)
  - A close relative with a known BRCA1 or BRCA2 gene mutation
  - At least two close blood relatives on the same side of the family with other hereditary breast and ovarian cancer (HBOC) syndrome-associated malignancies (prostate, pancreatic, melanoma)
  - Ethnicity associated with deleterious mutations, including Ashkenazi Jewish, Icelandic, Hungarian, Swedish, and Dutch

- Pancreatic, prostate (Gleason score of 7 or greater), epithelial ovarian/fallopian tube/primary peritoneal cancer with two or more close blood relatives with at least one of the following:
  - Breast cancer diagnosed at any age
  - Ovarian cancer diagnosed at any age
  - Pancreatic cancer diagnosed at any age
  - Prostate cancer (Gleason score of 7 or greater) diagnosed at any age

- Male breast cancer diagnosis
New qualifying criteria regarding family history

Individuals with a family history of at least one of the following (no personal history required):

- Relative with known BRCA1 or BRCA2 mutation
- Male relative with breast cancer
- Woman of Ashkenazi Jewish, Icelandic, Hungarian, Swedish, or Dutch ancestry with one or more of the following:
  - One or more first-degree relative with breast cancer or epithelial ovarian cancer
  - Two or more second-degree relative on same side of family with breast cancer
  - Two or more second-degree relative on same side of family with epithelial ovarian cancer
- Woman not of Ashkenazi Jewish, Icelandic, Hungarian, Swedish, or Dutch ancestry with one or more of the following:
  - First-degree or second-degree relative with breast cancer and one or more of the following:
    - Diagnosed at age 45 or younger
    - Diagnosed at age 50 or younger with unknown or limited family history
    - Diagnosed at age 50 or younger with one or more close blood relatives with breast cancer diagnosed at any age
    - Diagnosed at age 60 or younger with triple-negative breast cancer
  - First-degree or second-degree relative with two breast primary cancers with the first primary diagnosed at age 50 or younger
  - First-degree or second-degree relative with breast cancer diagnosed at any age, who in turn has one or more of the following:
    - One or more close blood relatives with breast cancer diagnosed at age 50 or younger
    - One or more close male blood relatives with breast cancer diagnosed at any age
    - One or more close blood relatives with epithelial ovarian cancer diagnosed at any age
    - Two or more close blood relatives with breast cancer diagnosed at any age
    - Two or more close blood relative with pancreatic cancer diagnosed at any age
    - Two or more close blood relative with prostate cancer (Gleason score of 7 or greater) diagnosed at any age
  - First-degree or second-degree relative with breast cancer diagnosed at any age who is of male gender
  - First-degree or second-degree relative with breast cancer who is of ethnicity associated with deleterious mutations, including Ashkenazi Jewish, Icelandic, Hungarian, Swedish, or Dutch
  - First degree or second-degree relative with epithelial ovarian cancer diagnosed at any age
First-degree or second-degree relative with pancreatic cancer diagnosed at any age who in turn has two or more close blood relative with one or more of the following:

- Breast cancer diagnosed at any age
- Ovarian cancer diagnosed at any age
- Pancreatic cancer diagnosed at any age
- Prostate cancer (Gleason score of 7 or greater) diagnosed at any age

First-degree or second-degree relative with prostate cancer (Gleason score of 7 or greater) diagnosed at any age, who in turn has two or more close blood relatives with one or more of the following:

- Breast cancer diagnosed at any age
- Ovarian cancer diagnosed at any age
- Pancreatic cancer diagnosed at any age
- Prostate cancer (Gleason score of 7 or greater) diagnosed at any age

Third-degree relative with breast or epithelial ovarian cancer, who in turn has one or more of the following:

- One close blood relative with epithelial ovarian cancer and another close blood relative with breast cancer diagnosed at age 50 or younger
- Two or more close blood relatives with breast cancer with at least one diagnosed at age 50 or younger
- Two or more close blood relatives with epithelial ovarian cancer diagnosed at any age

If the preceding criteria are not met, the PA request for the CPT codes in Table 1 will be denied as not medically necessary.

Questions regarding FFS PA should be directed to Cooperative Managed Care Services (CMCS) at 1-800-269-5720. Individual managed care entities (MCEs) establish and publish PA criteria within the managed care delivery system. Questions about managed care PA should be directed to the MCE with which the member is enrolled.