Purpose: To define the conditions under which MedStar Family Choice utilization management staff may authorize BRCA1/BRCA2 and BART testing.

Scope: MedStar Family Choice, MD; MedStar Family Choice, District of Columbia Healthy Families and Alliance.

Policy: It is the policy of MFC to authorize BRCA1/BRCA2 and BART testing by nurse utilization management staff as outlined in the criteria below. Requests that do not specifically meet the criteria may be submitted with supporting medical records, articles from the literature, etc. and will be reviewed by a Medical Director for a Medical Exception.

Background: MFC will follow the National Comprehensive Cancer Network (NCCN) Guidelines for determining the medical necessity of BRCA1, BRCA2 and BRAC Analysis® Large Rearrangement Test (BART) testing for hereditary breast and ovarian cancer gene mutations. BART testing is indicated when BRCA1/BRCA2 testing is indicated except when a known, specific familial mutation has been previously identified. These are the same guidelines followed by the MedStar Health Oncologist and genetic counselors.

Procedure:
MFC will approve BRCA1, BRCA2 and/or BART testing if at least one (1) of the following criteria are met:

A. An individual with a personal history of three or more of the following (especially if \( \leq 50 \) years of age and can include multiple primary cancers in the same individual): (1) breast cancer, (2) pancreatic cancer, (3) prostate cancer (Gleason \( \geq 7 \)), (4) melanoma, (5) sarcoma, (6) adrenocortical carcinoma, (7) brain tumors, (8) leukemia, (9) diffuse gastric cancer, (10) colon cancer, (11) endometrial cancer, (12) thyroid cancer, (13) kidney cancer, (14) dermatologic manifestations (e.g. trichilemmomas, acral keratoses, facial papules/oral papillomas) and/or macrocephaly, (15) hamartomatous polyps of gastrointestinal tract.

B. An individual with a personal history of breast cancer (including invasive and ductal carcinoma in situ breast cancers) and at least one (1) of the following:
   - Diagnosed age \( \leq 50 \) years old;
   - Two breast primaries, where two breast primaries include bilateral diseases or cases where there are two or more separate ipsilateral primary tumors;
   - Diagnosed age \( \leq 60 \) years old with triple negative breast cancer (ER neg, PR neg, HER neg);
   - Diagnosed at any age with one or more first-, second- or third-degree relatives with breast cancer diagnosed \( \leq 50 \) years old;
   - Diagnosed at any age with two or more first-, second- or third-degree relatives with breast cancer at any age;
   - Diagnosed at any age with one or more first-, second- or third-degree relatives with invasive ovarian cancer;
   - Diagnosed at any age with two or more first-, second- or third-degree relatives with pancreatic cancer at any age;
   - Personal history of pancreatic cancer at any age.

C. An individual with a personal history of an ovarian cancer such as fallopian tube cancer or primary peritoneal cancer, including non-mucinous and mucinous epithelial tumors.

D. An individual of Ashkenazi Jewish descent with breast, ovarian or pancreatic cancer at any age.

E. An individual with a personal history of male breast cancer.

F. An unaffected individual with:

A family history of three or more of the following (especially if the unaffected individual is \( \leq 50 \) years of age and can include multiple primary cancers in the same affected individual): (1) breast cancer, (2) pancreatic cancer, (3) prostate cancer (Gleason \( \geq 7 \)), (4) melanoma, (5) sarcoma, (6) adrenocortical carcinoma, (7) brain tumors, (8) leukemia, (9) diffuse gastric cancer, (10) colon cancer, (11) endometrial cancer, (12) thyroid cancer, (13) kidney cancer, (14) dermatologic manifestations (e.g. trichilemmomas,
acral keratoses, facial papules/oral papillomas) and/or macrocephaly, (15) hamartomatous polyps of gastrointestinal tract;

a. A first-, second- or third-degree relative with a known mutation of a cancer susceptibility gene in the family;
b. A first-, second- or third-degree relative with ≥ 2 breast cancer primaries in a single individual;
c. ≥ 2 first-, second- or third-degree relatives with breast cancer primaries on the same side of the family with at least one diagnosed ≤ 50 years old;
d. A first-, second- or third-degree relative with ovarian cancer;
e. A first-, second- or third-degree relative with male breast cancer;
f. A first-, second- or third-degree relative with breast cancer ≤ 45 years old.

* Note: In the situation of an unaffected individual with a significant family history, the testing of the unaffected individual should only be considered when test results for an affected family member are not available. When testing unaffected individuals, significant limitations may exist in interpreting the test results. Clinical judgment should be used to determine if the unaffected individual has reasonable likelihood of a mutation. Accordingly, these cases will be referred to a Medical Director for review.

* Note: only active MFC plan members are eligible for testing; family members of active MFC plan members are not eligible for testing under MFC coverage unless they themselves are active MFC plan members.

<table>
<thead>
<tr>
<th>Summary of Changes:</th>
<th>07/17:</th>
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<tbody>
<tr>
<td></td>
<td>• Changed Carol Attia to Theresa Bittle and updated Dr. Patryce Toye’s title from Senior Medical Director to Chief Medical Officer.</td>
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<tr>
<td></td>
<td>• Physician Advisor changes to Medical Director</td>
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<td></td>
<td>• NCCN 2017 updated language added</td>
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<tr>
<td>10/16:</td>
<td>• No changes</td>
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<tr>
<td>10/15:</td>
<td>G. Diagnosed age ≤ 50 years old and with one or more close blood relative with breast cancer at any age or with a limited family history, two or more close relative with pancreatic cancer, or one or more relative with prostate cancer (Gleason score ≥ 7)</td>
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<td>• ‘Epithelial ovarian’ changed to ‘invasive’ ovarian</td>
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