| | | |
|---|---|---|
| MedStar Family Choice | | |
| **ADMINISTRATIVE POLICY AND PROCEDURE** | | |
| **Policy #:** | **1407** | |
| **Subject:** | **BRCA1/BRCA2 and BART Testing** | |
| **Section:** | **Care Management** | |
| **Effective Date:** | **10/01/2013** | |
| **Revision Date(s):** | **10/15** | |
| **Review Date(s):** | **10/16** | |
| **Responsible Parties:** | **Patryce Toye, MD** | |
| **Responsible Department(s):** | **Utilization Management** | |
| **Regulatory References:** | **NCCN Guideline Version 2.2015 (dated 6/25/15) Hereditary Breast and/or Ovarian Cancer Syndrome Testing Criteria section.** | |
| **Approved:** | | |
| | **Carol Attia, RN<br>AVP, Care Management** | **Patryce A. Toye, MD<br>Senior Medical Director** |

**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 Physician Advisor 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 when the following criteria are met:

A. Individual from a family with known deleterious BRCA1/BRCA2 mutation

B. Personal history of breast cancer (including invasive and ductal carcinoma in situ breast cancers) and at least one (1) of the following:
   - Diagnosed age ≤ 45 years old
   - Two breast primaries when first breast cancer diagnosis occurred prior to age 50, where two breast primaries include bilateral diseases or cases where there are two or more separate ipsilateral primary tumors
   - Diagnosed age ≤ 50 years old and with one or more close blood relative[1] with breast cancer at any age or with a limited family history,[2] one or more close relative with pancreatic cancer, or one or more relative with prostate cancer (Gleason score ≥ 7)
   - Diagnosed age ≤ 60years old with triple negative breast cancer (ER neg, PR neg, HER neg)[2]
   - Diagnosed at any age with one or more close blood relative with breast cancer diagnosed ≤ 50 y
   - Diagnosed at any age with two or more close blood relatives with breast cancer at any age
   - Diagnosed at any age with one or more close blood relative with invasive ovarian cancer
   - Diagnosed at any age with two or more close blood relatives with pancreatic cancer or aggressive prostate cancer (Gleason score ≥ 7) at any age
   - Close male blood relative with breast cancer
   - Personal history of invasive ovarian cancer including fallopian tube cancer or primary peritoneal cancer
   - Personal background of ethnicity that is associated with higher mutational frequency (e.g. founder populations of Ashkenazi Jewish, Swedish, Icelandic, Hungarian and Dutch),
     Note: Testing for founder mutation(s), if available, should be performed first. Full sequencing may be considered if other HBOC criteria are met.

C. Personal history of invasive ovarian cancer including fallopian tube and primary peritoneal cancers.

D. Personal history of male breast cancer

E. Personal history of pancreatic cancer or aggressive prostate cancer (Gleason score ≥ 7) at any age with two or more close blood relatives with breast and/or ovarian (including fallopian tube cancer or primary peritoneal cancer and/or pancreatic or aggressive prostate cancer (Gleason score ≥ 7)

F. Family history, only: National Comprehensive Cancer Network (NCCN) guidelines state that significant limitations of interpreting test results for an unaffected individual should

be discussed. Testing of unaffected individuals should only be considered when an appropriate affected family member is unavailable for testing. Clinical judgment should be used to determine if the patient has reasonable likelihood of a mutation (NCCN, 2013). These cases will all be referred to the Physician Advisor for review.

**Footnotes:**

1. Close blood relatives are defined as follows:
    a. First degree relatives include parents, siblings and offspring
    b. Second degree relatives include half-brothers/sisters, aunts/uncles, grandparents, grandchildren and nieces/nephews affected on the same side of the family
    c. Third degree relatives include first cousins, great-aunts/uncles, great-grandchildren and great grandparents affected on same side of family
2. Limited family history is defined as having fewer than two known first-degree or second-degree female relatives or female relatives surviving beyond 45 years of age on either or both sides of the family. (e.g., individual who is adopted)
3. ER, PR and HR, i.e., estrogen, progesterone and herceptin receptor negative, respectively.

| | |
|---|---|
| **Summary of Changes:** | **10/16:**<br>• No changes<br>**10/15:**<br>• Diagnosed age ≤ 50 years old and with one or more close blood relative[1] with breast cancer at any age or with a limited family history,[2] one or more close relative with pancreatic cancer, or one or more relative with prostate cancer (Gleason score ≥ 7)<br>• 'Epithelial ovarian' changed to 'invasive' ovarian |