

MAXIMUS Federal Services, Inc.  
4000 IH 35 South, (8th Floor) 850Q  
Austin, TX 78704  
Tel: 512-800-3515 ♦ Fax: 1-877-380-6702

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**Notice of Independent Medical Review Decision**

**Reviewer's Report**

**DATE OF REVIEW:** January 28, 2013

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

BART testing (BRAC Analysis® Rearrangement Test).

**A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION**

M.D., Board Certified in Oncology and Hematology.

**REVIEW OUTCOME**

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
- Overturned (Disagree)**
- Partially Overturned (Agree in part/Disagree in part)

The requested BART testing (BRAC Analysis® Rearrangement Test) is not considered experimental/investigational for treatment of the patient's medical condition.

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

1. Request for a Review by an Independent Review Organization dated 11/30/12.
2. Confirmation of Receipt of a Request for a Review by an Independent Review Organization (IRO) dated 1/8/13.
3. Notice of Assignment of Independent Review Organization dated 1/8/13.
4. Letters dated 9/20/12 and 5/24/12.
5. Description of Requested Information for Precertification dated 4/3/12.
6. Prior Authorization Request Form dated 3/29/12.

7. BRAC Analysis Test Request Form dated 3/29/12.
8. Denial documentation dated 11/15/12, 10/19/12, and 5/3/12.

**PATIENT CLINICAL HISTORY [SUMMARY]:**

A review of the record indicates that the patient is a female with a personal history of right sided breast cancer diagnosed at age 41. The patient's family history includes a paternal aunt with breast cancer in her 50's, two paternal uncles and a paternal aunt had pancreatic cancer in their 50's, and her father had melanoma at age 75.

The provider has recommended BART testing (BRAC Analysis® Rearrangement Test) including CPT codes: 83891 - molecular diagnostics isolation or extraction of highly purified nucleic acid, each nucleic acid type (i.e., DNA or RNA); 83898 x 22 - molecular diagnostics amplification, target, each nucleic acid sequence; 83909 x 22 - molecular diagnostics separation and identification by high resolution technique (e.g., capillary electrophoresis), each nucleic acid preparation; 83912 - molecular diagnostics interpretation and report; 83904 x 22 - molecular diagnostics mutation identification by sequencing, single segment, each segment; and code 81213 x 1 – BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants.

**ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION**

BRCA testing is important in clinical oncology because bilateral mastectomy would eliminate a carrier's chance of developing breast cancer. Likewise, closer surveillance for ovarian cancer can be applied or the patient may choose salpingo-oophorectomy which would reduce the probability of developing this cancer. At the present time, genetic testing is not applied universally but rather to patients that exhibit family histories that are suggestive of inherited predispositions. A large study by Frank and colleagues performed BRCA testing in 10,000 individuals and related the presence of mutations to the family history. They found that family history included at least one first or second degree relative with breast or ovarian cancer. Thereafter, no distinction is made. This study is impressive for its size and for its separate analysis of individuals with Ashkenazi and non-Ashkenazi descent.

Genetic testing in this case is clinically indicated. BRCA1 and BRCA2 gene sequencing was approved but it does not pick up all point mutations and gene rearrangement needs to be tested by other methods (see Mazoyer). BRCA loss of function due to point mutation or rearrangement predisposes patients to increased risk for breast cancer and ovarian cancer. The detection methods are robust and are not experimental (see Welsch and King). Testing for BRCA gene rearrangement (BART) in this setting is medically appropriate for this patient's disease management. There is adequate peer-reviewed literature demonstrating that BART testing is likely to be more beneficial to the patient than other available diagnostic modalities.

Therefore, I have determined the requested BART testing (BRAC Analysis® Rearrangement Test) is not considered experimental/investigational for treatment of the patient's medical condition.

**A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
  
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
  
- MILLIMAN CARE GUIDELINES
  
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
  
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
  
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
  
- TEXAS TACADA GUIDELINES
  
- TMF SCREENING CRITERIA MANUAL
  
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

1. Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility: recommendation statement. *Ann Intern Med*, 2005 Sep 6;143(5):355-61.

2. Frank, T., et al. Clinical characteristics of individuals with germline mutations in BRCA1 and BRCA2: analysis of 10,000 individuals. *J Clin Oncol*, 2002 Mar 15;20(6):1480-90.

3. Mazoyer, S. Genomic rearrangements in the BRCA1 and BRCA2 genes. *Hum Mutat*, 2005 May;25(5):415-22.

4. Welsch, P. and King, M. BRCA1 and BRCA2 and the genetics of breast and ovarian cancer. *Hum Mol Genet*, 2001 Apr;10(7):705-13.

- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)