Medical Policy
Non-BRCA Breast Cancer Risk Assessment - e.g., OncoVue

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Policy Number: 188
BCBSA Reference Number: 2.04.57

Related Policies
- Genetic Testing of Hereditary Breast and/or Ovarian Cancer, #245

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

The OncoVue® and BREVAGen™ breast cancer risk tests are INVESTIGATIONAL as a method of estimating individual patient risk for developing breast cancer.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Service Type</th>
<th>Coverage Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare HMO BlueSM</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>This is not a covered service.</td>
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CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

**CPT Codes**
There is no specific CPT code for this service.

**ICD-9 Diagnosis Codes**
Investigational for all diagnoses.

**Description**
Tests that incorporate both clinical and genetic information have been developed to provide predictive information about breast cancer risk in asymptomatic women. Current methods of assessing breast cancer risk are imperfect, and genetic testing may offer improvements on current ability to assess breast cancer risk.

**Background**

*OncoVue®*
The OncoVue® Breast Cancer Risk Test (InterGenetics, Inc., Oklahoma City, OK) is a proprietary test that evaluates multiple, low-risk single nucleotide polymorphisms (SNPs) associated with breast cancer. The results are incorporated along with personal history measures to determine breast cancer risk at different times during adulthood. The test does not detect known high-risk genetic factors such as *BRCA* mutations (associated with hereditary breast and ovarian cancer, see Policy 2.04.02). OncoVue synthesizes the various genetic and medical history risk measures into a personalized single-risk estimate for premenopause, perimenopause, and postmenopause for each patient, with comparison to the average population risk at each of these life stages. The test is stated to be “an aid in the qualitative assessment of breast cancer risk…not intended as a stand-alone test for the determination of breast cancer risk in women.”

For women without a strong family history of breast cancer and at average risk prior to testing, OncoVue® purports to estimate a woman’s individual risk and place her in standard-, moderate-, or high-risk groups. The results are intended to help a woman and her physician decide if more frequent exams and/or more sophisticated surveillance techniques are indicated. For women already known to be at high risk based on a family history consistent with hereditary breast cancer, the test is represented as having added value by indicating greater or lesser risk at different life stages.

The OncoVue® test is available only through the Breast Cancer Risk Testing Network (BCRTN), described as a network of Breast Care Centers engaged in frontline genetic identification of breast cancer risk levels in their patients. BCRTN member centers will provide genetic breast cancer risk testing for their patients using OncoVue as part of a comprehensive education program to help OncoVue “at-risk” women understand their risk level and intervention strategies. BCRTN members will be selected for the network based on a number of criteria, including quality standards of care, level of breast cancer surveillance technology, and the capability of providing patient education on genetic testing and future risk management protocols. As of July 2013, 32 participating centers (36 locations), located in 20 states, were listed on the company website. OncoVue® is not listed in the Genetic Testing Registry of the National Center for Biotechnology Information.

*BREVAGen™*

BREVAGen™ evaluates 7 breast cancer-associated SNPs identified in genome-wide association studies (GWAS). Risk is calculated by multiplying the product of the individual SNP risks by the Gail model risk. BREVAGen has been evaluated for use in Caucasian women of European descent age 35 years and older. Like OncoVue, BREVAGen does not detect known high-risk mutations, e.g., *BRCA*. According to the BREVAGen website, “suitable candidates” for testing include women with a Gail lifetime risk of 15% or greater; with high lifetime estrogen exposure (e.g., early menarche and late menopause); or with relatives diagnosed with breast cancer. BREVAGen is not suitable for women with previous diagnoses of lobular carcinoma in situ, ductal carcinoma in situ, or breast cancer, since the Gail model cannot calculate breast...
cancer risk accurately for such women, or for women with an extensive family history of breast and ovarian cancer.

**Summary**

There is a lack of published detail regarding OncoVue® and BREVAGen™ test validation, supportive data, and management implications. The available data suggest that OncoVue and BREVAGen may add predictive accuracy to the Gail Model. However, the degree of improved risk prediction may be modest, and the clinical implications are unclear. There is insufficient evidence to determine whether using breast cancer risk estimates from OncoVue or BREVAGen in asymptomatic individuals changes management decisions and improves patient outcomes. Therefore, OncoVue and BREVAGen testing for breast cancer risk assessment are considered investigational.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>7/2014</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>1/2011</td>
<td>Updated with added references.</td>
</tr>
<tr>
<td>5/1/2010</td>
<td>New policy effective 5/1/2010 describing non-coverage</td>
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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:

- [Medical Policy Terms of Use](#)
- [Managed Care Guidelines](#)
- [Indemnity/PPO Guidelines](#)
- [Clinical Exception Process](#)
- [Medical Technology Assessment Guidelines](#)

**References**

3. Jupe ER, Pugh TW, Knowlton NS. Breast cancer risk estimation using the OncoVue model compared to combined GWAS single nucleotide polymorphisms. 2009 San Antonio Breast Cancer Symposium; Abstract 3177.