

## Corporate Medical Policy

### Non-BRCA Breast Cancer Risk Assessment (OncoVue)

**File Name:** non-brca\_breast\_cancer\_risk\_assessment\_(oncovue)  
**Origination:** 11/2009  
**Last CAP Review:** 3/2012  
**Next CAP Review:** 3/2013  
**Last Review:** 3/2012

#### Description of Procedure or Service

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OncoVue is a genetic test that is intended to provide predictive information about breast cancer risk in asymptomatic women. Current methods of assessing breast cancer risk, e.g. the Gail Model, are imperfect, and genetic testing may offer improvements on current ability to assess breast cancer risk.

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). 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 members 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 August 2011, 36 Breast Care Centers, located in 20 states, were listed on the company Web site available online at: <http://www.intergenetics.com/>.

**Related Policies:**

Genetic Testing for Breast and Ovarian Cancer

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical**

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*language and/or specific clinical indications for its use, please consult your physician.*

## Policy

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**Non-BRCA Breast Risk Assessment (OncoVue) is considered investigational for all applications. BCBSNC does not cover investigational services or procedures.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Non-BRCA Breast Cancer Risk Assessment (OncoVue) is covered

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Not applicable.

## When Non-BRCA Breast Cancer Risk Assessment (OncoVue) is not covered

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The OncoVue® Breast Cancer Risk Test is considered investigational as a method of estimating individual patient risk for developing breast cancer. BCBSNC does not cover investigational services.

## Policy Guidelines

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There is a lack of published detail regarding the OncoVue® test validation, supportive data, and management implications. The available data suggests that OncoVue 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 in asymptomatic individuals changes management decisions and improves patient outcomes.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes:* There is no specific code for this service.

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BCBSNC may request medical records for determination of medical necessity. When medical records are

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requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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Intergenetics. What is OncoVue? Retrieved 10/5/09 from [http://www.intergenetics.com/intergenetics/oncovue\\_testresults.html](http://www.intergenetics.com/intergenetics/oncovue_testresults.html)

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.57, 8/13/09

Senior Medical Director - 10/2009

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.57, 9/16/10

Specialty Matched Consultant Advisory Panel – 3/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.57, 9/1/2011

Medical Director – 12/2011

Specialty Matched Consultant Advisory Panel – 3/2012

## Policy Implementation/Update Information

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11/9/09 New medical policy issued. Reviewed with Senior Medical Director 10/16/2009. The OncoVue® Breast Cancer Risk Test is considered investigational as a method of estimating individual patient risk for developing breast cancer. BCBSNC does not cover investigational services. Notice given 11/9/2009. Effective date is 2/16/2010. (btw)

6/22/10 Policy Number(s) removed (amw)

4/26/11 Specialty Matched Consultant Advisory Panel review March 30, 2011. “Description” section revised. “Policy Guidelines” updated. No change to policy intent. References added. (btw)

1/24/11 “Description” and “Policy Guidelines” sections updated. No change to policy intent. Medical Director review 12/14/2011. References added. (btw)

4/17/12 Specialty Matched Consultant Advisory Panel review. No change to policy. (btw)

3/21/2012

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.