Protocol

Non-BRCA Breast Cancer Risk Assessment (e.g., OncoVue)

(20457)

Medical Benefit		**Effective Date**: 01/01/14	**Next Review Date**: 09/14
Preauthorization	No	**Review Dates**: 09/10, 09/11, 09/12, 09/13	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

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. 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 seven 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.

As of July 2013, approximately 40 participating centers in 17 states were listed on the company website. BREVAGen™ is listed in the Genetic Testing Registry of the National Center for Biotechnology Information.

Regulatory Status

No test combining the results of SNP analysis with clinical factors to predict breast cancer risk has been approved or cleared by the U.S. Food and Drug Administration (FDA). These are offered as laboratory-developed tests; that is, tests developed and used at a single testing site. Laboratory developed tests, as a matter of enforcement discretion, have not been traditionally regulated by FDA in the past. They do require oversight under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and the development and use of laboratory developed tests is restricted to laboratories certified as high complexity under CLIA.

Under the current regulatory program, CLIA requires that laboratories demonstrate the analytical validity of the tests they offer. However, there is no requirement for a test to demonstrate either clinical validity or clinical utility.

Related Protocols:

Genetic Testing for Hereditary Breast and/or Ovarian Cancer

Use of Common Genetic Variants to Predict Risk of Nonfamilial Breast Cancer

Corporate Medical Guideline

The OncoVue® and BREVAGen™ breast cancer risk tests are considered **investigational** as methods of estimating individual patient risk for developing breast cancer.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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