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Protocol

Assays of Genetic Expression in Tumor Tissue as a Technique to Determine Prognosis In Patients With Breast Cancer

(20436)

Effective July 1, 2007

Contracts Affected:
All Community Blue HMO
Community Blue MCO 501
*****Senior Blue/Medicare PPO**
Traditional Blue

*The following protocol contains medical necessity criteria for Assays of Genetic Expression in Tumor Tissue as a Technique to Determine Prognosis In Patients With Breast Cancer services rendered on or after July 1, 2007 for BlueCross BlueShield of Western New York (BlueCross BlueShield) contracts. If these criteria are not met, reimbursement will be denied and the patient cannot be billed. **Prior approval is required.** Please note that payment for covered services is subject to the limitations noted in the above-referenced contracts and the patient's eligibility at the time the services are rendered.*

Description

For women with early-stage breast cancer, adjuvant chemotherapy provides the same proportional benefit regardless of prognosis. However, the absolute benefit of chemotherapy depends on the baseline risk of recurrence. For example, women with the best prognosis have small tumors, are estrogen receptor positive, and lymph node negative. These women have an approximately 15% baseline risk of recurrence; approximately 85% of these patients would be disease-free at 10 years with tamoxifen treatment alone and could avoid the toxicity of chemotherapy if they could be accurately identified. Conventional risk classifiers estimate recurrence risk by considering criteria such as tumor size, type, grade, and histologic characteristics; hormone receptor status; and lymph node status. However, no single classifier is considered a gold standard, and several common criteria have qualitative or subjective components that add variability to risk estimates. As a result, more patients are treated with chemotherapy than can benefit. Better predictors of baseline risk could help women, who prefer to avoid chemotherapy if assured that their risk is low, make better treatment decisions in consultation with their physicians.

Recently, several groups have identified panels of gene expression markers ("signatures") that appear to predict the baseline risk of breast cancer recurrence after surgery, radiation therapy, and hormonal therapy (for hormone receptor-positive tumors) in women with node-negative disease. Three gene expression tests are commercially available in the United States: Oncotype DX™ (a 21-gene RT-pcr assay), MammaPrint®, and the Breast Cancer Gene Expression Ratio. If these panels are more accurate than current conventional classifiers, they could be used to aid chemotherapy decision-making, where current guidelines do not strongly advocate its use, without negatively affecting disease-free and overall survival outcomes.

Corporate Medical Guideline

The use of Oncotype DX™ to determine recurrence risk for deciding whether or not to undergo adjuvant chemotherapy may be considered **medically appropriate** in women with breast cancer meeting the following characteristics:

- unilateral, non-fixed tumor;

- hormone receptor positive (that is ER-positive or PR-positive);
- HER2-negative;
- tumor size 0.6–1 cm with moderate/poor differentiation or unfavorable features OR tumor size >1cm;
- node negative (lymph nodes with micrometastases (less than 2 mm in size) are considered node negative for this policy statement); AND
- who will be treated with adjuvant endocrine therapy, e.g., tamoxifen.

All other indications for the 21-gene RT-pcr assay (e.g., Oncotype DX™) are considered **investigational** because it is unproven outside the investigational setting.

The use of other gene expression assays (e.g., MammaPrint® or the Breast Cancer Gene Expression Ratio) for any indication is considered **investigational** because it is unproven outside the investigational setting.

Oncotype DX should only be ordered after surgery and subsequent pathology examination of the tumor have been completed. The test should be ordered in the context of a physician-patient discussion regarding risk preferences and when the test result will aid the patient in making decisions regarding chemotherapy.

Unfavorable features that may prompt testing in tumors from 0.6 to 1 cm. in size include the following: angiolymphatic invasion, high histologic grade, or high nuclear grade.

For explanation of experimental and investigational refer to the Technology Assessment Protocol.

*** Senior Blue/Medicare PPO ***

For Senior Blue/Medicare PPO this is **medically appropriate** for patients with estrogen-receptor positive, node-negative carcinoma of the breast, when performed within 6 months of diagnosis and the results will be used to determine the management of the patient.

Prior approval is required. BlueCross BlueShield fully expects that only appropriate and medically necessary services will be rendered. BlueCross BlueShield reserves the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures.

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Next Review Date

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