



P R O V I D E R B U L L E T I N

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**To: All Indiana Health Coverage Programs Physicians,
Hospitals, and Laboratories**

**Subject: HER-2/neu Gene Detection Test and HER2 Protein
Expression Test**

Overview

According to the American Cancer Society, an estimated 178,700 new cases of invasive breast cancer were reported in the United States in 1998. An estimated 43,900 deaths were due to breast cancer in 1998. Breast cancer is the second major cause of cancer death for women. Mortality rates have continued to decline and these decreases are likely due to earlier detection and improved treatment.

Many advances have been made in the treatment of breast cancer. The human HER-2/neu gene (also known as c-erbB-2, ERBB2 or neu) encodes a protein called HER2 protein or p185^{HER2}. This protein receptor plays a role in controlling cell growth and division. In 25 to 30 percent of patients with breast cancer, the HER2 protein is overexpressed as part of the malignant transformation and tumor progression. Overexpression of HER2 protein has been shown to contribute to the progression of the cancer and is associated with poor clinical outcome. Targeted antibody therapy to HER2 has played a significant role in the treatment of metastatic breast cancer. Clinical trial results show that the HER2 protein on breast cancer cells is an important target for cancer therapies and that trastuzumab (HERCEPTIN[®]) can be an effective treatment, whether used by itself or in combination with other chemotherapy drugs.

Several types of HER2 overexpression tests are available. One type is a semiquantitative immunohistochemical assay that measures the overexpression of HER2 protein (an example is the HercepTest[®]).

Another type is a gene probe assay, which detects the qualitative presence of the gene amplification in human breast tissue (for example, Oncor's INFORM[®] HER-2/neu Gene Detection Test). This test is a DNA probe assay known as fluorescent *in situ* hybridization (FISH).

In an effort to improve the health and survival of Indiana Health Coverage Programs (IHCP) members with breast cancer, the IHCP will provide reimbursement for FDA approved HER2 protein overexpression and gene detection tests effective January 14, 2000.

Coverage Guidelines

As providers are aware, the FDA-approved indications for HER2 protein overexpression and gene detection tests are:

- For HER2 protein overexpression tests (HercepTest[®]), as an aid in assessment of patients for whom trastuzumab (HERCEPTIN[®]) is being considered.
- For HER-2/neu gene detection tests, as an adjunct to existing clinical and pathological information and as an aid to stratify breast cancer patients with a primary, invasive, localized breast carcinoma, and who are lymph node negative, for risk for recurrence or disease-related death. This test is used as a prognostic indicator.

Prior Authorization is not required.

The ICD-9-CM Diagnosis Codes that support the medical necessity of HER2 protein overexpression and gene detection tests are:

- 174.0–174.9 Malignant neoplasm of the female breast
- 175.0–175.9 Malignant neoplasm of the male breast

The ordering physician must have documentation in the member's medical records to support the medical necessity of the test(s) ordered. Laboratories performing the test must have documentation that laboratory personnel education has been completed in the proper performance of the test and reporting of the test results. Reimbursement will be provided only to Clinical Laboratory Improvement Amendments (CLIA) certified laboratories.

Billing Information

A HER2 protein overexpression test (for example, HercepTest[®]) is billed using the following codes:

- **88342** Immunocytochemistry (including tissue immunoperoxidase), each antibody
- **88365** Tissue *in situ* hybridization, interpretation and report

The HER-2/neu Gene Detection Test (for example, Oncor's INFORM[®]) is billed using the following codes:

- **83892** Enzymatic digestion
- **88271** Molecular cytogenetics; DNA probe, each (for example, FISH)
- **88274 or 88275** Interphase *in situ* hybridization, analyze 25-99 cells (88274) or 100-300 cells (88275). Only one (1) of these two (2) codes should be billed.
- **88291** Cytogenetics and molecular cytogenetics, interpretation and report

Additional Information

Please direct any questions regarding this bulletin and the policy to the Health Care Excel Medical Policy department at (317) 347-4500. Questions regarding billing procedures referenced in this bulletin may be directed to EDS Customer Assistance at (317) 655-3240 locally or 1-800-577-1278 outside of Indianapolis.