Local Coverage Determination (LCD):
Gene Expression Profiling Panel for use in the Management of Breast Cancer Treatment (L33586)

Contractor Information

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction</th>
<th>State(s)</th>
</tr>
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<tr>
<td>First Coast Service Options, Inc.</td>
<td>A and B MAC</td>
<td>09101 - MAC A</td>
<td>J - N</td>
<td>Florida</td>
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<td>First Coast Service Options, Inc.</td>
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<td>09302 - MAC B</td>
<td>J - N</td>
<td>Virgin Islands</td>
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LCD Information

Document Information

LCD ID
L33586

Original ICD-9 LCD ID
L28849

LCD Title
Gene Expression Profiling Panel for use in the Management of Breast Cancer Treatment

 Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 01/01/2018

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date
N/A

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CMS National Coverage Policy
Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

42 CFR 410.32
42 CFR 410.42
42 CFR 414.510
42 CFR 414.50
CMS Change Request 5573, dated 08/17/2007
CMS Manual System, Pub 100-02, Medicare Benefit Policy Manual, Chapter 6, Section 20
CMS Manual System, Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 80.1
CMS Manual System, Pub 100-04, Medicare Claims Processing Manual, Chapter 16, Sections 40.8 and 120.1 CMS Manual System, Pub 100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.4.1.2

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

Genomics focuses on how the complex set of genes in the genome are expressed and interact to regulate cell behavior in health and disease. An important genomic parameter is the pattern of gene expression, which can be ascertained by measuring the levels of expressed ribonucleic acid (RNA). To date, therapeutic decisions for locally advanced breast cancer are mainly guided by clinicopathological parameters, such as patient age and functional status, comorbidities, estrogen receptor status, tumor grade, tumor size and lymph node status. Clinical studies have shown that incorporation of gene expression signatures into clinical risk stratification may be useful for prognostic and therapeutic strategies in breast carcinoma.

The application of gene expression profiling using Oncotype DX™ is employed to identify patients who are predicted to obtain the most therapeutic benefit from adjuvant tamoxifen and may not require adjuvant chemotherapy. The Oncotype DX™ (Genomic Health, Redwood City, California), uses reverse transcription polymerase chain reaction (RT-PCR) to determine the expression of a panel of 21 genes isolated from formalin-fixed, paraffin-embedded tissue (FPET).

A Recurrence Score™ (RS) is calculated from the gene expression results using a proprietary Oncotype DX™ algorithm, which is then used to assign a patient to one of three groups by estimated risk of distant recurrence: low, intermediate and high. Patients with high recurrence scores (RS) appear to achieve relatively more benefit from adjuvant chemotherapy.

This test is provided throughout the United States by the Clinical Laboratory Improvement Amendments (CLIA)-regulated laboratory of Genomic Health, Inc. in Northern California. Therefore, when this test is a Part B service, most or all coverage decisions for Medicare beneficiaries are made by the Part B contractor serving Genomic Health, Inc., which is National Heritage Insurance Company (NHIC).

Prosigna™ Breast Cancer Prognostic Gene Signature Assay uses an mRNA analysis of 58 genes using hybrid capture on formalin-fixed paraffin-embedded tissue to determine the prognostic algorithm of breast cancer reported as a risk score. The Prosigna Assay is intended for use as a prognostic indicator for distant recurrence-
free survival at 10 years. It is indicated for postmenopausal women with Stage I/II lymph node-negative or Stage II lymph node-positive (one to three positive nodes) hormone receptor-positive breast cancer who have undergone surgery in conjunction with locoregional treatment consistent with standard of care. For each patient, the Prosigna Assay reports the Prosigna Score (referred to as Risk of Recurrence Score, or ROR Score) and a risk category based on both the Prosigna Score and nodal status. Node-negative patients are classified as low, intermediate, or high risk, while node-positive patients are classified as low or high risk.

MammaPrint® has been prospectively, clinically validated for use in early stage (I and II) breast cancer patients regardless of Estrogen Receptor (ER) or HER2 status, with a tumor size ≤5.0 cm, and 0-3 positive lymph nodes (LN0-1), with no special specifications for N1mi pathology. This differentiates MammaPrint from other multi-gene assays in use today that have only shown predictive value in ER positive, HER2 negative, lymph node (LN) negative patients. MammaPrint is also indicated for patients with ER negative tumors. There are no exclusion criteria based on histopathologic tumor type (i.e. ductal, lobular, mixed, etc.) or age. MammaPrint is predictive for pre-and post-menopausal women.

**Indications**

The application of gene expression profiling using Oncotype DX™ will be considered medically reasonable and necessary, with case by case review as needed, when used to assess the need for adjuvant chemotherapy in patients with recently diagnosed breast cancer (six months or less have elapsed) when all of the following criteria are met:

- Breast cancer is nonmetastatic (node-negative) (lymph nodes with micrometastases are not considered positive); and
- Estrogen positive breast carcinoma with 1-3 positive nodes; and
- Breast cancer is unilateral and non-fixed (i.e., tumor not adhered to chest wall); and
- Breast tumor is hormone receptor-positive (estrogen receptor (ER)-positive or progesterone receptor (PR)-positive); and
- Breast tumor is HER2-receptor negative; and
- Breast tumor size is 0.6-1 cm with moderate/poor differentiation or unfavorable features (e.g., angiolymphatic invasion, high nuclear grade, or high histologic grade), **OR** tumor size is >1 cm; and
- Breast tumor is stage 1 or stage II; and
- Breast cancer will be treated with hormonal therapy; and
- Adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age and/or significant co-morbidities); and
- Testing is being done specifically to guide the decision as to whether or not adjuvant chemotherapy will be used and, prior to testing the patient and oncologist have discussed the potential results of the test and agree to use the results to guide therapy (i.e., the patient will forgo adjuvant chemotherapy if Oncotype DX™ score is low).

This LCD also provides limited coverage of the Prosigna™ Breast Cancer Prognostic Gene Signature Assay to patients who meet the following criteria consistent with the FDA indications for use:

Post-menopausal female either:

- ER+, lymph node-negative, Stage I or II breast cancer; or
- ER+, lymph node-positive (1-3 positive nodes), Stage II breast cancer.

Testing is being done specifically to guide the decision as to whether or not adjuvant chemotherapy will be used and, prior to testing the patient and oncologist have discussed the potential results of the test and agree to use the results to guide therapy (i.e., the patient will forgo adjuvant chemotherapy if Prosigna™ score is low).

This LCD also provides limited coverage of the MammaPrint® breast cancer recurrence signature test for patients who meet the following criteria, consistent with the FDA indications for use:
• Early stage (I and II) breast cancer patients, male or female: **AND**
• Breast tumor ER positive or ER negative; **AND**
• Breast tumor is HER-2 receptor negative **AND**
• Breast tumor size greater than 0.5 cm but less than or equal to 5.0 cm; **AND** or HER2 status;

**AND**

• Lymph node negative or 1-3 positive axillary lymph nodes (non-distant metastatic); **AND**
• Individual has been assessed (eg, Adjuvant! Online) and determined to be a candidate for adjuvant chemotherapy (ie, chemotherapy is not disallowed due to other factors, such as advanced age or comorbidities); **AND**
• Specimen submitted for analysis is formalin fixed paraffin embedded or fresh or frozen tumor tissue

Medical tests are covered only when ordered by the treating oncologist, when necessary for diagnosis or treatment decisions, and when used in patient care (42 CFR 410.32).

**Limitations**

Claims for Prosigna™ or MammaPrint® testing will be denied when testing does not meet all of the above criteria.

All other uses of MammaPrint®, Prosigna™ or OncoType DX™ are considered experimental or investigational; specifically, the following indications:

- To predict response to specific chemotherapy regimens
- Repeat MammaPrint®, Prosigna™ or OncoType DX™ testing or testing of multiple tumor sites in the same patient

In a clinical trial, this test would typically be used for data collection and would not be considered a routine cost and, therefore, this service would not be billed.

Gene expression profiling as a technique of managing the treatment of breast cancer is considered investigational and not medically necessary when a gene profiling test other than MammaPrint®, Prosigna™ or the OncoType DX™ breast cancer assay is used, including but not limited to:

1. Breast Cancer Gene Expression Ratio
2. Rotterdam 76-Gene Signature
3. The 41-gene signature assay
4. Amsterdam 70-Gene Profile

Genomic Health public documents filed with the United States Securities and Exchange Commission (SEC) note that OncoType DX™ is not currently regulated by the Food and Drug Administration (FDA) (neither approved nor disapproved), but this status could be subject to change. Determinations of the FDA, which directly affect the legality of marketing status would override this Local Coverage Determination (LCD).

**Summary of Evidence**

N/A

**Analysis of Evidence**

(Rationale for Determination)

N/A

**Coding Information**

**Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all
Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

012x  Hospital Inpatient (Medicare Part B only)
013x  Hospital Outpatient
014x  Hospital - Laboratory Services Provided to Non-patients
085x  Critical Access Hospital

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

0301   Laboratory - Chemistry

CPT/HCPCS Codes

Group 1 Paragraph: N/A

Group 1 Codes:
81519  ONCOLOGY (BREAST), MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 21 GENES, UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS RECURRENCE SCORE

Group 2 Paragraph: N/A

Group 2 Codes:
81520  ONCOLOGY (BREAST), MRNA GENE EXPRESSION PROFILING BY HYBRID CAPTURE OF 58 GENES (50 CONTENT AND 8 HOUSEKEEPING), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS A RECURRENCE RISK SCORE

Group 3 Paragraph: N/A

Group 3 Codes:
81521  ONCOLOGY (BREAST), MRNA, MICROARRAY GENE EXPRESSION PROFILING OF 70 CONTENT GENES AND 465 HOUSEKEEPING GENES, UTILIZING FRESH FROZEN OR FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS INDEX RELATED TO RISK OF DISTANT METASTASIS

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: (For 81519)

Group 1 Codes:

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>DESCRIPTION</th>
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<tr>
<td>C50.011 - C50.929</td>
<td>Malignant neoplasm of nipple and areola, right female breast - Malignant neoplasm of unspecified site of unspecified male breast</td>
</tr>
<tr>
<td>Z17.0*</td>
<td>Estrogen receptor positive status [ER+]</td>
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Group 1 Medical Necessity ICD-10 Codes Asterisk Explanation: *Code first malignant neoplasm of breast (C50.xxx). ICD-10 code Z17.0 should not be billed as the primary diagnosis; therefore, this diagnosis code (Z17.0) must be billed with another diagnosis code from the range of codes listed above.

Group 2 Paragraph:
(For 81520)
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<th>ICD-10 Code</th>
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<tr>
<td>C50.011 - C50.019</td>
<td>Malignant neoplasm of nipple and areola, right female breast - Malignant neoplasm of nipple and areola, unspecified female breast</td>
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<tr>
<td>C50.111 - C50.119</td>
<td>Malignant neoplasm of central portion of right female breast - Malignant neoplasm of central portion of unspecified female breast</td>
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<tr>
<td>C50.211 - C50.219</td>
<td>Malignant neoplasm of upper-inner quadrant of right female breast - Malignant neoplasm of upper-inner quadrant of unspecified female breast</td>
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<tr>
<td>C50.311 - C50.319</td>
<td>Malignant neoplasm of lower-inner quadrant of right female breast - Malignant neoplasm of lower-inner quadrant of unspecified female breast</td>
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<td>C50.411 - C50.419</td>
<td>Malignant neoplasm of upper-outer quadrant of right female breast - Malignant neoplasm of upper-outer quadrant of unspecified female breast</td>
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<td>C50.511 - C50.519</td>
<td>Malignant neoplasm of lower-outer quadrant of right female breast - Malignant neoplasm of lower-outer quadrant of unspecified female breast</td>
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<td>C50.611 - C50.619</td>
<td>Malignant neoplasm of axillary tail of right female breast - Malignant neoplasm of axillary tail of unspecified female breast</td>
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<td>C50.811 - C50.819</td>
<td>Malignant neoplasm of overlapping sites of right female breast - Malignant neoplasm of overlapping sites of unspecified female breast</td>
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<td>C50.911 - C50.919</td>
<td>Malignant neoplasm of unspecified site of right female breast - Malignant neoplasm of unspecified site of unspecified female breast</td>
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<td>D05.00 - D05.92</td>
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**Group 2 Medical Necessity ICD-10 Codes Asterisk Explanation:** *Code first malignant neoplasm of breast (C50.xxx) or carcinoma in situ of breast (D05.xx). ICD-10 code Z17.0 should not be billed as the primary diagnosis; therefore, this diagnosis code (Z17.0) must be billed with another diagnosis code from the range of codes listed above.

**Group 3 Paragraph:**

(For 81521 - MammaPrint®)

**Group 3 Codes:**

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<td>Malignant neoplasm of nipple and areola, right female breast - Malignant neoplasm of nipple and areola, left female breast</td>
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<td>C50.021 - C50.022</td>
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<td>C50.111 - C50.112</td>
<td>Malignant neoplasm of central portion of right female breast - Malignant neoplasm of central portion of left female breast</td>
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<td>C50.121 - C50.122</td>
<td>Malignant neoplasm of central portion of right male breast - Malignant neoplasm of central portion of left male breast</td>
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<td>C50.211 - C50.212</td>
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<td>C50.221 - C50.222</td>
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<td>C50.521 - C50.522</td>
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<td>C50.611 - C50.612</td>
<td>Malignant neoplasm of axillary tail of right female breast - Malignant neoplasm of axillary tail of unspecified female breast</td>
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<td>ICD-10 Code</td>
<td>DESCRIPTION</td>
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<td>C50.621 - C50.622</td>
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<td>C50.811 - C50.812</td>
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<td>C50.821 - C50.822</td>
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<td>C50.911 - C50.912</td>
<td>Malignant neoplasm of unspecified site of right female breast - Malignant neoplasm of unspecified site of left female breast</td>
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**Group 3 Medical Necessity ICD-10 Codes Asterisk Explanation:** *Code first malignant neoplasm of breast (C50.xxx). ICD-10 code Z17.0 or Z17.1 should not be billed as the primary diagnosis; therefore, these diagnosis codes (Z17.0, Z17.1) must be billed with another diagnosis code from the range of codes listed above.

**ICD-10 Codes that DO NOT Support Medical Necessity**

Additional ICD-10 Information
N/A

**General Information**

**Associated Information**

**Documentation Requirements**

The following documentation should be available for review upon request:

- Patient history and physical; and
- Pathology report; and
- Documentation which indicates all of the following:

  A. The results of the test are expected to play a significant role in management of the patient; and
  B. The patient is a candidate for possible adjuvant chemotherapy (i.e., chemotherapy is not precluded due to other factors) and testing is being done specifically to guide the decision as to whether or not adjuvant chemotherapy will be used; and,
  C. The genomic information derived from this test has been integrated with copathological parameters, such as patient age and functional status, comorbidities and tumor grade.

The test should only be ordered after surgery and subsequent pathological 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.

Providers should not submit additional information with the claim. First Coast may request it separately with an additional documentation request (ADR) letter.

**Utilization Guidelines**

It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

**Sources of Information**
First Coast Service Options Inc., reference LCD numbers – L28882, L29184, L29343


**Bibliography**

N/A

### Revision History Information

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<td>01/01/2018</td>
<td>R6</td>
<td>Approving this LCD version to relate Articles A56045 and A56049 to the LCD.</td>
<td>Other</td>
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<tr>
<td>01/01/2018</td>
<td>R5</td>
<td>Revision Number: 3 Publication: December 2017 Connection LCR A/B2018-001</td>
<td>Revisions Due To CPT/HCPSCS Code Changes</td>
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<td>Revision History Explanation</td>
<td>Reason(s) for Change</td>
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<td><strong>Explanation of Revision:</strong> Annual 2018 HCPCS Update. CPT code 0008M was deleted and replaced with CPT code 81520 in the “CPT/HCPCS Codes-Group 2 Codes” and “ICD-10 Codes that Support Medical Necessity – Group 2 Codes” sections of the LCD. In addition, CPT code 81479 was removed and replaced with CPT code 81521 in the CPT/HCPCS Codes-Group 3 Codes” and “ICD-10 Codes that Support Medical Necessity – Group 3 Codes” sections of the LCD. The effective date of this revision is based on date of service. 01/01/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this policy.</td>
<td>• Revisions Due To CPT/HCPCS Code Changes</td>
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<tr>
<td>03/17/2016</td>
<td>R4</td>
<td>Revision Number: 2</td>
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<td>Publication: February 2017 Connection LCR A/B2017-004</td>
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<td>Explanation of revision: CPT code 81479 was added to this LCD with limited coverage indications and diagnosis codes as a result of an LCD reconsideration request. The effective date of this revision is based on date of service.</td>
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<tr>
<td>01/21/2016</td>
<td>R3</td>
<td>Typographical error corrected</td>
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<tr>
<td>01/21/2016</td>
<td>R2</td>
<td>Revision Number: 1</td>
<td>• Reconsideration Request</td>
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<tr>
<td></td>
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<td>Publication: December 2015 Connection LCR A/B2015-024</td>
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<td>Explanation of revision: CPT code 0008M was removed from the Noncovered Services LCD (L33777) and placed in this LCD with limited coverage indications and diagnosis codes as a result of an LCD reconsideration request. The effective date of this revision is based on date of service.</td>
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<tr>
<td>10/01/2015</td>
<td>R1</td>
<td>3/13/2015: The language and/or ICD-10-CM diagnoses were updated to be consistent with the current ICD-9-CM LCD’s language and coding.</td>
<td>• Revisions Due To CPT/HCPCS Code Changes</td>
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**Associated Documents**

**Attachments**
N/A

**Related Local Coverage Documents**

Article(s)
A56045 - Gene expression profiling panel for use in the management of breast cancer treatment revision to the Part A and Part B "coding guidelines” article
A56049 - Gene Expression Profiling Panel for use in the Management of Breast Cancer Treatment Coding Guideline

**Related National Coverage Documents**
N/A
Keywords
N/A