Northern Light Beacon Health

Employee Health Plan

Policy Number: PA-018
Last Review Date: 02/09/2017
Effective Date: 01/01/2018

Policy

Northern Light Employee Health Plan considers **Gene expression testing** for breast cancer medically necessary for the following indications:

Prosigna is considered medically necessary ***only for post-menopausal women who meet all of the following criteria***:

1. Diagnosed with Stage I or II breast cancer within the previous six months; and
2. Lymph node-negative or Stage II with 1-3 positive nodes; and
3. Estrogen receptor (ER) positive tumor; and
4. Her2 negative tumor; and
5. The woman would be a candidate for adjuvant chemotherapy and
6. The result of the test will guide the decision whether or not to use chemotherapy; and
7. The woman would choose to receive chemotherapy if offered.

Mammaprint is considered medically necessary ***only for women who meet all of the following criteria***:

1. Diagnosed with stage I or II breast cancer within the previous six months; and
2. Lymph node-negative; and
3. Tumor smaller than 5.0 centimeters; and
4. Estrogen receptor (ER) positive or negative tumor; and
5. Her2 negative tumor; and
6. The woman would be a candidate for adjuvant chemotherapy and
7. The result of the test will guide the decision whether or not to use chemotherapy; and
8. The woman would choose to receive chemotherapy if offered.

Oncotype DX is considered medically necessary ***only for women who meet all the following criteria***:

1. Diagnosed with Stage I or II breast cancer within the previous six months; and
2. Lymph node-negative; and
3. Estrogen receptor (ER) positive tumor; and
4. Her2 negative tumor; and
5. The woman would be a candidate for adjuvant chemotherapy and
6. The result of the test will guide the decision whether or not to use chemotherapy; and
7. The woman would choose to receive chemotherapy if offered.

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Breast Cancer Index (**BCI**) (bioTheranostics) is considered medically necessary only for women who meet all of the following criteria and have Medicare coverage:

1. Post-menopausal female with non-relapsed, ER+ breast cancer,
2. Was lymph node negative,
3. Is completing five years of tamoxifen therapy,
4. Patient must be eligible for consideration of extended endocrine therapy based on published clinical trial data or practice guidelines,
5. Physician or patient is concerned about continuing anti-hormonal therapy because of documented meaningful toxicity or possible significant patient specific side effects,
6. The test results will be discussed with the patient (including the limitations of the testing method, the risks and benefits of either continuing or stopping the therapy based on the test, and current cancer management guidelines).

Limitations

1. **A maximum of one genomic assay per breast tumor is considered medically necessary and therefore second or subsequent genomic assays on the same tumor are not covered**.
2. Gene expression testing for breast cancer will *only be covered if the test is ordered by an oncologist*.
3. Since gene expression assays analyze ribonucleic acid (RNA) and RNA is unstable:
    - Assay samples are to be obtained at the time of tumor excision;
    - Time from excision to fixation should be less than 1 hour (see College of American Pathologists/American Society of Clinical Oncology (CAP/ASCO) protocol; reference below);
    - Formalin fixed paraffin blocks that are greater than six months old should not be tested.
4. Evolent Health considers Mammaprint, Oncotype DX, and Prosigna to be **experimental/investigational for any other uses, reasons, or tissue type**.

Background

About one in eight women will develop breast cancer during their lifetime in the United States. Breast cancer is the second most commonly diagnosed cancer among women behind skin cancer. Breast cancer refers to a malignant tumor in the breast caused by an uncontrolled growth in cells and it is always caused by a genetic abnormality. Leading risk factors include increasing in age and being of the female sex.

If breast cancer is detected, various tests can be performed for additional insight on the rate of growth, likelihood of spreading or return and the potential effectiveness of treatment options. Mutigene tests are one set of tests utilized and they can include:

- Oncotype DX: multigene test that predicts whether Stage I or Stage II breast cancer that is estrogen receptor positive and node negative will spread to other parts of the body.
- MammaPrint: multigene test that predicts whether Stage I or Stage II breast cancer that is node negative will spread to other parts of the body.
- Prosigna: multigene test for post-menopausal women that predicts whether Stage I or Stage II breast cancer that is estrogen receptor positive and node negative will spread to other parts of the body

If these tests indicate a high chance of spreading, chemotherapy may be given to lower the risk.

Oncotype DX Scores (risk of recurrence)

- 0 < 18: low risk
- 18-31: intermediate risk
- ≥ 31: high risk

Prosigna Scores (risk of recurrence):

- 0-40: low risk
- 41-60:intermediate risk
- 61-100: high risk

Variations:

Commercial
Breast Cancer Index (BCI) will deny as Experimental and Investigational

Codes:

CPT/HCPCS Codes	
Code	Description
S3854	Gene expression profiling panel for use in the management of breast cancer
0008M	Oncology (breast), mRNA analysis of 58 genes using hybrid capture, on formalin-fixed paraffin-embedded (FFPE) tissue, prognostic algorithm reported as a risk score
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
84999	Unlisted chemistry procedure

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Disclaimer:
Northern Light Employee Health Plan medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of Northern Light Employee Health Plan and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

Northern Light Employee Health Plan reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.