

Breast Cancer Treatment and Prognostic Algorithmic Tests

- I. The use of the breast cancer treatment and prognostic algorithmic test Oncotype DX Breast Recurrence Score is considered **medically necessary** in all members, regardless of gender, when:
 - A. The member has primary breast cancer that is ductal/NST, lobular, mixed or micropapillary, **AND**
 - B. The member's tumor is hormone receptor-positive (estrogen receptor-positive or progesterone receptor-positive), **AND**
 - C. The member's tumor is human epidermal growth factor receptor 2 (HER2)-negative, **AND**
 - D. The member is considering treatment with adjuvant therapy (e.g., tamoxifen, aromatase inhibitors, immunotherapy), **AND**
 - E. The member is status post tumor resection and surgical axillary nodal staging, **AND**
 1. The member meets one of the following (regardless of menopausal status):
 - a) Tumor is greater than 0.5 cm and node negative (pN0), **OR**
 - b) Lymph nodes are pN1mi (2mm or smaller axillary node metastases), **OR**
 - c) Lymph nodes are pN1 (1-3 positive nodes).
- II. The use of the breast cancer treatment and prognostic algorithmic test Oncotype DX Breast Recurrence Score is considered **investigational** for all other indications.

DEFINITIONS

1. **Adjuvant** therapy is a medication (such as chemotherapy or endocrine therapy) given after the surgical removal of a cancerous tumor.
2. **Ductal/NST** is a ductal breast cancer of no special type (NST), meaning the cancer cells have no features that classify them as a specific type of breast cancer when examined by microscope.

REFERENCES

1. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 6.2024.
https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf