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.

RATIONALE AND REFERENCES

Breast Cancer Treatment and Prognostic Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Breast Cancer (4.2025)

Oncotype DX for breast cancer is a 21-gene expression assay and is one of many gene expression assays used to aid in determining adjuvant systemic therapy. This guideline recommends the 21-gene expression assay for both prognosis and treatment decisions in patients of either sex (p. BINV-J 1 of 2, BINV-N 1 of 5). Per NCCN, the breast tumor must be either ductal/NST, lobular, mixed, or micropapillary, and it also must be hormone receptor positive (either Estrogen receptor or Progesterone receptor), and HER2 negative (p. BINV-6, BINV-7, BINV-8).

Females (sex assigned at birth) with postmenopausal breast tumors must be considering chemotherapy and have one of the following:

- A tumor that is 0.5 cm or larger (p. BINV-6)
- A tumor that is pN1mi (2 mm or smaller axillary node metastases) (p. BINV-6)
- A tumor that is pN1 (1–3 positive nodes) (p. BINV-6).

Females (sex assigned at birth) with premenopausal breast tumors must be a candidate for chemotherapy and have one of the following:

- A tumor that is 0.5 cm or larger and pN0 (p. BINV-7)
- A tumor that is pN1mi (2 mm or smaller axillary node metastasis) (p. BINV-7)
- A tumor that is pN1 (1-3 positive nodes) (p. BINV-7).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer 4.2025 https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

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.