BREAST CANCER TREATMENT AND PROGNOSTIC ALGORITHMIC TESTS

I.   The use of the breast cancer treatment and prognostic algorithmic test Oncotype DX Breast Recurrence Score (81519, S3854) is considered **medically necessary** in all patients, 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 meets one of the following (regardless of menopausal status):

      1.   Tumor is greater than 0.5 cm and node negative (pN0), **OR**

      2.   Lymph nodes are pN1mi (2mm or smaller axillary node metastases), **OR**

      3.   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 (81519, S3854) is considered **investigational** for all other indications.

DEFINITIONS

1. **Ductal/NST breast cancer:** Ductal cancer that is of no special type (NST), meaning the cancer cells have no features that class them as a special type of breast cancer when examined by microscope.

2. **Adjuvant therapy:** Medication (such as chemotherapy or endocrine therapy) given after the surgical removal of a cancerous tumor.

REFERENCES

1. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2024. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf