Breast Cancer Prognostic Algorithmic Tests

I. The use of a breast cancer prognostic algorithmic test (i.e., EndoPredict, Prosigna, MammaPrint) is considered **medically necessary** when:

   A. The member is female (sex assigned at birth), **AND**

   B. The member meets at least one of the following:

   1. Postmenopausal status, **OR**

   2. Greater than 50 years of age, **AND**

   C. The member has primary breast cancer that is ductal/NST, lobular, mixed or micropapillary, **AND**

   D. The member's tumor is estrogen receptor-positive, **AND**

   E. The member's tumor is human epidermal growth factor receptor 2 (HER2)-negative, **AND**

   F. The member is considering treatment with adjuvant therapy (e.g, tamoxifen, aromatase inhibitors, immunotherapy), **AND**

   G. The member has had axillary nodal staging and has the following node status:

   1. pN0 (nodes negative pathologically), **OR**

   2. pN1mi or pN1 (1-3 nodes positive pathologically)[1].

II. The use of a breast cancer prognostic algorithmic test (i.e., EndoPredict, Prosigna, MammaPrint) in individuals with 4 or more positive nodes is considered **investigational**.

III. The use of the breast cancer prognostic algorithmic test Prosigna in individuals with 1-3 node positive breast cancer is considered **investigational**.

IV. The use of a breast cancer prognostic algorithmic test (i.e., EndoPredict, Prosigna, MammaPrint) in men (sex assigned at birth) with breast cancer is considered **investigational**.

    V.   The use of a breast cancer prognostic algorithmic test (i.e., EndoPredict, Prosigna, MammaPrint) is considered **investigational** for all other indications.

[1] Prosigna is indicated for node negative disease, but **not** for disease with 1-3 positive nodes. EndoPredict and Mammaprint are indicated for node negative disease and for disease with 1-3 positive nodes.

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
2. Andre F, Ismaila N, Allison KH, et al. Biomarkers for Adjuvant Endocrine and Chemotherapy in Early-Stage Breast Cancer: ASCO Guideline Update [published correction appears in J Clin Oncol. 2022 Aug 1;40(22):2514]. *J Clin Oncol*. 2022;40(16):1816-1837. doi:10.1200/JCO.22.00069