

Breast Cancer Prognostic Algorithmic Tests

- I. The use of a breast cancer prognostic algorithmic test (i.e., EndoPredict, Prosigna, MammaPrint) (S3854, 81520, 81521, 81522, 81523) is considered **medically necessary** when:
 - A. The member is female, **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 (for example, tamoxifen, aromatase inhibitors, immunotherapy), **AND**
 - G. The member has the following node status:
 1. Node negative, **OR**
 2. 1-3 positive nodes*.
- II. The use of a breast cancer prognostic algorithmic test (i.e., EndoPredict, Prosigna, MammaPrint) (S3854, 81520, 81521, 81522, 81523) in individuals with 4 or more positive nodes is considered **investigational**.
- III. The use of the breast cancer prognostic algorithmic test Prosigna (81520) in individuals with node-negative breast cancer is considered **investigational**.
- IV. The use of a breast cancer prognostic algorithmic test (i.e., EndoPredict, Prosigna, MammaPrint) (S3854, 81520, 81521, 81522, 81523) in men with breast cancer is considered **investigational**.

- V. The use of a breast cancer prognostic algorithmic test (i.e., EndoPredict, Prosigna, MammaPrint) (S3854, 81520, 81521, 81522, 81523) is considered **investigational** for all other indications.

*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.

NOTES AND DEFINITIONS

1. **Ductal/NST breast cancer** is ductal cancer that is 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.

REFERENCES

1. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2023. 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