Endopredict® - Gene Expression Profiling for Managing Breast Cancer Treatment

Policy Number:	**M20191011051**
Effective Date:	**12/1/2019**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☐ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒MediSource Connect; ☒Child Health Plus; ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth Independent Health's criteria for the use of the **Endopredict®** test for managing breast cancer treatment.

Policy:

Background:

Breast cancer is the most common cancer in American women, with 1 in 8 women developing breast cancer during their lifetime in the United States. EndoPredict® is a multigene expression profiling assay designed to assess prognosis in early-stage breast cancer patients. The EndoPredict® assay analyzes the gene expression level of 8 breast cancer related genes and 4 reference genes within a breast tumor to determine an Endopredict score. The score corresponds to a specific likelihood of breast cancer reoccurrence within 10 years of the initial diagnosis. Test results are designed to guide decisions regarding adjuvant systemic chemotherapy in patients following surgical management of breast cancer.

The National Comprehensive Cancer Network considers the EndoPredict® assay suitable for prognostic purposes with evidence category 2A and the American Society of Clinical Oncology's clinical practice guidelines states if a patient has ER/PgR-positive, HER2-negative (node-negative) breast cancer, the clinician may use the EndoPredict® 12-gene risk score to guide decisions on adjuvant systemic chemotherapy.

Commercial and Self-Funded: EndoPredict® is covered utilizing MCG guidelines.

Medicare Advantage:
There is currently a Local Coverage Article (LCA) and a Local Coverage Determination (LCD) for EndoPredict®. Please refer to the link listed in the Reference section for Medicare Advantage members.

MediSource, MediSource Connect, and Essential Plan: EndoPredict® is covered utilizing the criteria below. NYS Medicaid criteria for EndoPredict® is in accordance with current National Comprehensive Cancer Network (NCCN) Guidelines. In between policy reviews, providers are encouraged to follow the most recent NCCN guidance.

Clinical Indications

Per New York State coverage criteria, EndoPredict®, prognostic gene expression test assists practitioners in making determinations regarding the effective and appropriate use of chemotherapy in female or male patients with malignant neoplasms of the breast, when **ALL** of the following criteria are met:

- When the test results will aid the patient and practitioner in making the decision regarding chemotherapy (i.e., when chemotherapy is a therapeutic option and is not precluded due to any other factor)
- The tumor is estrogen receptor positive (ER+), progesterone receptor positive (PR+), or both
- Human epidermal growth factor receptor 2 (HER2) negative
- Tumor is T1 or T2
- Node-negative or 1-3 positive nodes

Pre-Authorization Required? Yes ☒ No ☐

Preauthorization is required for this service.

1. The ordering /rendering laboratory is responsible for securing Prior Authorization for Medically Necessary molecular diagnostic testing.

2. The ordering / referring physician is responsible for submitting all relevant member-level clinical information to the rendering laboratory to support the Prior Authorization request.

3. Claims received for molecular diagnostic testing lacking Prior Authorization will deny to the responsibility of the rendering laboratory, and Independent Health members shall not be billed. Therefore, it is imperative that rendering laboratories, with clinical information supplied by ordering / referring physicians, secure and verify Prior Authorization in accordance with the process above and clinical requirements above.

Definitions

EndoPredict® is a real-time, reverse transcription PCR (RT-PCR) assay of RNA isolated from tumor tissue samples that are either from a formalin-fixed paraffin-embedded (FFPE) block or a core needle biopsy. The test identifies 12 genes related to tumor proliferation and hormone receptor activity.

References

Related Policies, Processes and Other Documents
N/A

Non-Regulatory references
Andre F, Ismaila N, Henry NL, et al. Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women With Early-Stage Invasive Breast Cancer: ASCO Clinical Practice Guideline Update-Integration of Results From TAILORx. J Clin Oncol. 2019 Aug 1;37(22):1956-1964.

Cardoso F, Kyriakides S, Ohno S et al. Early breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment, and follow-up. Ann Oncol. 2019 Jun 24.

Foukakis T, Bergh J, Hurvitz S. Deciding when to use adjuvant chemotherapy for hormone receptor-positive, HER2-negative breast cancer. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed on July 1, 2026.

Foukakis T, Bergh J. Prognostic and predictive factors in early, non-metastatic breast cancer. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed on July 1, 2026.

Krop I, Ismaila N, Andre F, et al. Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women with Early-Stage Invasive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Focused Update. J Clin Oncol. 2017 Aug 20;35(24):2838-2847.

Müller BM, Keil E, Lehmann A, et al. The EndoPredict Gene-Expression Assay in Clinical Practice - Performance and Impact on Clinical Decisions. PLoS One. 2013 Jun 27;8(6):e68252.

National Comprehensive Cancer Network (NCCN) [web site]. Breast Cancer. Version 4.2026-June 12, 2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
Accessed July 1, 2026.

National Institute for Care Excellence (NICE) [web site]. Tumour profiling tests to guide adjuvant chemotherapy decisions in early breast cancer. 09 May 2024. Available at: https://www.nice.org.uk/guidance/htg719
Accessed July 1, 2026.

Symplr Inc. Molecular Test Assessment EndoPredict (Myriad Genetics). Houston, TX. December 2020.

Regulatory References

Centers for Medicare and Medicaid (CMS) [web site]. Local Coverage Article Billing and Coding. Available at: Molecular Pathology Procedures (A56199) Available at: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56199&ver=129&LCDId=35000&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=1&bc=AAQAAAIAIAAA&=
Accessed July 1, 2026.

Centers for Medicare and Medicaid (CMS) [web site]. Local Coverage Determination (LCD):Molecular Pathology Procedures (L35000) Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35000&ver=155&=
Accessed July 1, 2026.

New York State Medicaid Update [web site]; Volume 35; Number 8; July 2019: page 5. Available at: https://www.health.ny.gov/health_care/medicaid/program/update/2019/jul19_mu.pdf
Accessed July 1, 2026.

New York State Medicaid Update [web site]; Volume 42; Number 6; May 2026. Available at: https://www.health.ny.gov/health_care/medicaid/program/update/2026/no06_2026-05.htm
Accessed July 21, 2026.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
9/1/2026	Health Care Services	Revised
10/1/2025	Health Care Services	Reinstated
4/1/2025	Health Care Services	Discontinued
10/1/2024	Health Care Services	Revised
9/1/2024	Health Care Services	Reviewed
10/1/2023	Health Care Services	Reviewed
10/1/2022	Health Care Services	Revised
11/1/2021	Health Care Services	Revised
11/1/2020	Health Care Services	Revised