

The Department of Vermont Health Access Clinical Criteria

Subject: Gene Expression Profiling for the Management of Breast Cancer

Last Review: May 5, 2023*

Past Revisions: January 26, 2021, September 1, 2020, August 14, 2019,
June 19, 2019, June 1, 2018, November 1, 2017, August 26, 2015

***Please note: Most current content changes will be highlighted in yellow.**

Description of Service or Procedure

Gene expression profiling tests such as Oncotype DX® Breast Recurrence Score, EndoPredict®, and Breast Cancer Index® are tools used to predict risk for recurrence of breast cancer and its response to therapy. These prognostic and predictive factors are relevant for patients diagnosed with early, non-metastatic breast cancer. Decisions can then be made regarding the addition of adjuvant chemotherapy to a treatment regimen or whether to treat with endocrine therapy alone.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at <https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules>

- 7102.2 Prior Authorization Determination
- 7405 Laboratory and Radiology Services
- 4.101 Medical Necessity for Covered Services
- 4.104 Medicaid Non-Covered Services
- 4.106 Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services

Coverage Position

Gene Expression Profiling using Oncotype DX® Breast Recurrence Score, EndoPredict®, Breast Cancer Index®, or MammaPrint® may be covered for members:



- When the device is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described in their Vermont State Practice Act, Statute, or rule who is knowledgeable regarding this testing, and who provides medical care to the member AND
- When the clinical criteria below are met.

Coverage Criteria

Gene expression profiling is covered by Vermont Medicaid in accordance with the National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology for breast cancer for the following tests:

- **Oncotype DX®**
- **EndoPredict®**
- **Breast Cancer Index®**
- **MammaPrint®**

Please find this guideline at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

Note: The following test is a Vermont Medicaid noncovered service and if requested, will be considered on a case-by-case basis through the Vermont Medicaid exceptions process found at: <https://dvha.vermont.gov/members/vermont-medicaid-programs/member-information/coverage-exceptions>

- **Prosigna®**
 - Medicare Local Coverage Determination (LCD): <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=36811>

Considerations: Providers requesting this test should provide pre- and post-test genetic counseling for the member and family, if applicable.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT) exception: Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence- based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

One test per breast cancer diagnosis is approved.

Type of service or procedure covered

Gene expression profiling tests for breast cancer as outlined above.

Type of service or procedure not covered (this list may not be all inclusive)

The use of more than one type of test (if covered by Medicaid) to determine necessity of adjuvant therapy in breast cancer (Oncotype Dx® Breast, Breast Cancer Index®, EndoPredict®, Prosigna®, MammaPrint®) is considered experimental and investigational.

The use of these tests for any other purpose not outlined in this policy will not be covered.

Coding guidelines

Please see the Medicaid Portal at <http://vtmedicaid.com/#/feeSchedule> for fee schedules, code coverage, and applicable requirements.

References

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