



Guidelines for Medical Necessity Determination for Gene Expression Profiling Tests for Breast Cancer

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth needs to determine medical necessity for gene expression profiling tests for breast cancer. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 401.000 and 450.000 and Subchapter 6 of the *Independent Clinical Laboratory Manual* for information about coverage, limitations, service conditions, and other prior-authorization (PA) requirements. Providers serving members enrolled in a MassHealth-contracted managed care organization (MCO) or a MassHealth-contracted integrated care organization (ICO) should refer to the MCO's or ICO's medical policies for covered services.

MassHealth reviews requests for PA on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

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SECTION I. GENERAL INFORMATION

Analysis of the expression of genes between normal and malignant cells in an individual with breast cancer results in a gene expression profile for breast cancer. Gene expression profiling can be used to sub-classify breast cancer, predict disease prognosis, and determine likely response to therapy. In particular, it can estimate the risk of breast cancer recurrence in women with early stage breast cancer and identifies who would benefit most from cytotoxic chemotherapy in addition to surgical treatment. This test spares those women who would derive little or no benefit from treatment with adjuvant chemotherapy. Several gene expression profiling tests are in varying stages of development and clinical investigation. Of these tests, MassHealth covers Oncotype DX™, a multiplex, 21-gene, real-time, PCR-based assay. Oncotype DX™ quantifies the likelihood of disease recurrence in women with stages I and II hormone receptor-positive, human epidermal growth factor receptor-2 (HER2) negative, lymph node-negative, invasive breast cancer. A mathematic algorithm is used to generate a breast cancer recurrence score (RS) that classifies patients as low- (RS<18), intermediate- (RS, 18-30), or high-risk (RS≥31). Studies have validated the use of these genes and the RS in predicting recurrence risk. They have also determined that high-risk patients receive the maximum benefit from chemotherapy compared to low- and intermediate-risk patients. MassHealth considers approval for coverage of Oncotype DX™ on an individual, case-by-case basis, in accordance with 130 CMR 450.204. MassHealth considers other gene expression profiling tests experimental and investigational.

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SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for Oncotype DX™ on a combination of clinical data and the presence of indicators that would affect the relative risks and benefits of the procedure. These criteria include, but are not limited to, all of the following:

1. gene expression profiling testing is being done specifically to guide the decision as to whether adjuvant chemotherapy will be used. The patient and oncologist must have discussed the potential results of the test and agree to use the results to guide therapy before the testing; and
2. the gene expression profiling test is ordered by the treating oncologist or by a pathologist who submits documentation of a tumor board discussion; and
3. breast cancer is newly diagnosed; and
4. breast cancer histology is ductal, lobular, mixed, or metaplastic; and
5. breast tumor is hormone receptor-positive (estrogen receptor (ER)-positive and/or progesterone receptor (PR)-positive); and
6. breast tumor is HER2-receptor negative; and
7. breast cancer is non-fixed (i.e., tumor not adhered to chest wall); and
8. the breast cancer tumor is greater than 5 mm; and
9. the tumor stage is pT1, pT2, or pT3; is nonmetastatic (pN0) or has axillary lymph node micrometastases less than or equal to 2 mm (pN1mi); and
 - a. breast cancer will be treated with hormonal therapy; and
 - b. adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age and/or significant co-morbidities).
10. gene expression profiling may be considered on a case-by-case basis for patients with tumors with one to three ipsilateral axillary nodes with micrometastases, as described in section II. A.9., that otherwise meet the criteria above.
11. the test must be performed by a MassHealth contracting laboratory facility.

B. NONCOVERAGE

MassHealth does not consider gene expression profiling to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following.

1. To predict response to specific chemotherapy regimens.
2. Repeat testing or testing of multiple tumor sites in the same patient.
3. Gene expression profiling tests other than Oncotype DXTM.

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SECTION III. SUBMITTING CLINICAL DOCUMENTATION

Requests for PA for gene expression profiling must be accompanied by clinical documentation that supports the medical necessity for this procedure.

A. DOCUMENTATION OF MEDICAL NECESSITY MUST INCLUDE ALL OF THE FOLLOWING.

1. A copy of the completed test request form, which has been signed and dated by the oncologist or pathologist
2. The primary diagnosis name, current ICD code, and date of diagnosis
3. Secondary diagnosis name(s) and current ICD codes(s) pertinent to comorbid conditions(s)
4. The most recent medical evaluation, including a summary of the medical history, the last physical exam, co-morbid conditions, and current medications
5. Summary of previous surgeries and hospitalizations
6. Report of results of the pathological evaluation of the breast tumor, including size, histology, tumor grade, the presence or absence of hormone and HER2 receptors, and tumor staging, including the presence or absence of affected lymph nodes and their sizes
7. Documentation of current therapy and intention to use results of testing to guide the decision as to whether adjuvant chemotherapy will be used
8. Other clinical information that MassHealth may request

B. Clinical information must be submitted by the treating oncologist or by a pathologist who also submits documentation of a tumor board discussion. Providers are strongly encouraged to submit requests electronically. Providers must submit all information pertinent to the diagnosis using the Provider Online Service Center (POSC) or by completing a MassHealth Prior Authorization Request form (using the PA-1 paper form found at www.mass.gov/masshealth) and attaching pertinent documentation.

The PA-1 form and documentation should be mailed to the address on the back of the form. Questions about POSC access should be directed to the MassHealth Customer Service Center at 1-800-841-2900.

Code Definition

81519 Oncology (breast), mRNA, gene expression profiling by real time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score

SELECT REFERENCES

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3. Dowsett M, Cuzick J, Wale C, Forbes J, et al. Prediction of Risk of Distant Recurrence Using the 21-Gene Recurrence Score in Node-Negative and Node-Positive Postmenopausal Patients With Breast Cancer Treated With Anastrozole or Tamoxifen: A TransATAC Study. 2010; 28(11): 1829-1834.
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11. Paik S, Shak S, Tang G, Kim C, et al. A multigene assay to predict recurrence of Tamoxifen-treated, node-negative breast cancer. *NEJM*. 2004; 351(27):2817-26.
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These Guidelines are based on review of the medical literature and current practice in gene-expression profiling for breast cancer. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of proposed treatment. Some language used in this communication may be unfamiliar to other readers; in this case, contact your health care provider for guidance or explanation.

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