

**MEDICAL ASSOCIATES HEALTH PLANS
HEALTH CARE SERVICES POLICY AND PROCEDURE MANUAL
POLICY NUMBER: PP 67**

POLICY TITLE: TUMOR CHEMOSENSITIVITY AND CHEMORESISTANCE ASSAYS

POLICY STATEMENT: Tumor sensitivity assays are tests utilized in cancer treatment to predict the sensitivity of tumors to chemotherapeutic medications, to screen potential anticancer agents, predict the effect of these agents on tumors of individual patients and identify the most effective treatment protocols with the intended result of increasing patient survival, i.e. deliver a specific chemotherapeutic protocol that is based on a member's tumor cells response to a specific chemotherapeutic agent(s). There are a variety of in vitro assays, but they all share four basic steps: isolation of tumor cells, incubation of cells with anti-cancer drugs, assessment of cell growth or survival, and interpretation of results.

POLICY: MAHP does not cover tumor chemosensitivity and chemoresistance assays as they are considered experimental and investigational as there is insufficient evidence that these assays improve health outcomes and lack of evidence that they improve the management of the patient.

1. Medical Associates Health Plans has an established procedure to formalize the process by which the Plan evaluates the inclusion of new medical technologies and the new application of existing technologies, including medical procedures, pharmaceutical, behavioral health procedures, and devices into the benefit package. In order to meet criteria for coverage, a technology must meet the following:
 - a. The technology must have final approval from the appropriate government regulatory bodies.
 - b. The scientific evidence must permit conclusions concerning the effect of the technology in health outcomes.
 - c. The technology must improve the net health outcome.
 - d. The technology must be as beneficial as any established alternatives.
 - e. The improvement must be attainable outside the investigational setting.
2. Certification of tumor chemosensitivity and chemoresistance assays will be reviewed on an annual basis. This review will be based upon:
 - a. scientific research
 - b. current medical literature and
 - c. in accordance with current community standards
3. Upon review, should these technologies meet the above stated criteria; the technology will be reviewed by the Utilization Management (UMC) and Quality Improvement (QIC) Committees, with the ultimate decision resting with the Medical Associates Clinic Board of Directors (MAC BOD).

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4. Once the medical technology has been given the final approval by the UMC, QIC and MAC BOD, the decision is also communicated to the Senior Management of MAHP via email and/or at the next Management meeting.
5. Policies changes will be communicated, as appropriate, to network physicians and providers and enrollees.

Oncotype DX Testing for Breast Cancer Treatment Management – Apollo Criteria

Indications and rationale for the test

Determines risk for recurrent tumor growth in certain patients with breast cancer. Considered **medically necessary** for patients with breast cancer stage I-II, who are node-negative and estrogen receptor positive and will receive hormonal therapy.” (CareFirst 2006)

Aetna criteria: Oncotype Dx is considered medically necessary “to assess necessity of adjuvant chemotherapy in women with recently diagnosed breast tumors, where all of the following criteria are met:

1. Breast cancer is nonmetastatic (node negative¹); and
2. Breast tumor is estrogen receptor positive; and
3. Breast tumor is HER2 receptor negative or breast tumor is HER2 receptor positive and less than 1 cm in diameter. (Rationale: adjuvant chemotherapy with trastuzumab (Herceptin) is considered to be medically necessary regardless of an Oncotype Dx score for HER2 receptor positive lesions 1 cm or more in diameter); and
4. Adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age and/or significant co-morbidities); *and*
5. Member and physician (prior to testing) have discussed the potential results of the test and agree to use the results to guide therapy (i.e., member will forgo adjuvant chemotherapy if Oncotype Dx score is low).

Either standard node dissection negative by hematoxylin and eosin (H&E) staining or sentinel node negative by H&E staining (if sentinel node is negative by H&E, but immunoassay is positive, then still considered node negative for this purpose).” (Aetna 2006)

BC BS IL criteria: “The use of Oncotype DX to determine risk of cancer recurrence and help physicians and patients decide whether or not to undergo adjuvant chemotherapy **may be considered medically necessary** when the following criteria are met:

- A. Surgery and subsequent pathology examination of the tumor having been completed; **AND**
- B. The test is ordered by the oncologist who is caring for the patient; **AND**
- C. There is documented physician-patient discussion about how those results will guide the patient in decision-making on chemotherapy; **AND**
- D. The patient’s breast cancer will be treated with hormonal therapy; **AND**
- E. The cancer has the following characteristics:
 - Unilateral, non-fixed tumor, **AND** Lymph node-negative, **AND**
 - Hormone-receptor-positive (ER-positive [estrogen receptor positive, ER+] or PR-positive [progesterone receptor positive, PR+]), **AND** HER2 (human epidermal growth factor receptor 2)-negative, **AND**
 - Tumor size of either:
 1. 0.6-1 centimeter (cm) with moderate or poor differentiation or unfavorable features, or
 2. >1 cm.

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All other indications for Oncotype DX are considered experimental, investigational and unproven.

Note: Medicare members must meet Medicare criteria.

Oncotype DX Testing in Stage II Colon Cancer Patients – Approved for Medicare & Commercial Patients

It tests tumor tissue for twelve genes to develop a recurrence score that patients and their doctors can use in combination with other clinical information to make decisions about having chemotherapy after surgery. The test *does not predict* whether or not chemotherapy will reduce risk of recurrence, but it *does indicate risk for recurrence*.

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Date

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Date

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