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Medical Policy

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Title: Serum Tumor Markers for Breast Malignancies

Professional
Original Effective Date: March 26, 2002
Revision Date(s): September 30, 2002; June 13, 2003; March 27, 2014; March 18, 2015; March 2, 2016; January 18, 2017; February 15, 2018; April 24, 2019
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Current Effective Date: March 18, 2015
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DESCRIPTION

Serum tumor markers are molecules or substances shed by a tumor into the circulation where they can be detected and quantitated. Noncirculating tumor markers include those that can be detected histochemically or cytogenetically on a tissue sample.

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Examples of the latter include the HER2 oncoprotein, detected by immunohisto-chemistry on a subset of breast cancers, and the Philadelphia chromosome, which is a cytogenetic marker for chronic myelogenous leukemia.

Serum tumor markers have been investigated in many malignancies, including most prominently myeloma (ie, beta-2 microglobulin), germ cell tumors (ie, alpha feto-protein, human chorionic gonadotropin), and prostate cancer (ie, PSA). The HER2 oncoprotein extracellular domain has been studied as a serum tumor marker in breast and other malignancies. Carcinoembryonic antigen (CEA) has also been widely investigated in gastrointestinal malignancies. This policy focuses on specific tumor markers for breast malignancies.

For breast cancer, the most extensively investigated serum tumor markers besides HER2 are those associated with the MUC-1 gene. The MUC-1 gene encodes a cell-associated mucin-like antigen, and different antibodies may be used to detect different epitopes. CA 15-3 and CA 27.29 are 2 related monoclonal antibodies that detect epitopes encoded by the MUC-1 gene. While much of the literature has focused on the use of CA 15-3, it has been largely replaced by CA 27.29, which is reportedly more sensitive.

Since serum tumor markers can also be detected in normal or benign lesions, significantly elevated circulating levels may occur with malignancy by one or more of the following mechanisms: (1) overexpression of the antigen by malignant cells; (2) a large tumor burden; and/or (3) slower clearance of the marker. For example, since most tumor markers are cleared by the liver, liver abnormalities (whether benign, malignant, or inflammatory) may elevate tumor marker concentrations due to impaired clearance. Because most tumor markers are not unique to malignancy, cut-off points must be established for normal versus abnormal marker levels. In contrast, serial monitoring of serum tumor markers in a setting of established malignancy may not require such cut-off points. Various clinical applications of serum tumor markers can be broadly divided into 2 categories, those involving a single measurement and those involving serial measurements.

Single Measurement of Serum Tumor Markers

Diagnosis

Diagnosis of a suspected malignancy or unknown primary requires a tumor marker that is relatively specific for a given tumor. Since most tumor markers, including those

discussed above, are expressed both in normal, benign conditions and malignancies, serum tumor markers are rarely used for diagnosis. Exceptions include human chorionic gonadotropin (HCG) and alpha feto-protein (AFP), whose elevated levels are both consistently seen with germ cell tumors. In addition, markedly elevated prostate-specific antigen (PSA) is highly suggestive of a prostatic malignancy.

Prognosis

A key determinant of initial therapy for epithelial tumors is their surgical resectability, generally excluded by the presence of distant metastases. Elevated tumor markers may relate to tumor burden. Thus they may suggest presence of, and prompt a more vigorous search for, metastatic disease not detected by routine clinical examination prior to surgery. For example, markedly elevated levels of PSA are highly suggestive of metastatic prostate cancer.

Choosing a Treatment Regimen

Certain cancer therapies specifically target a tumor marker protein. In addition, patients whose tumors express a given marker may be more likely to benefit from certain chemotherapy regimens. Thus, for example, breast cancer patients with HER2-positive tumors are often treated with regimens that combine trastuzumab (which targets the HER2 molecule) plus an anthracycline-based chemotherapy regimen (which has a greater impact on outcomes than other regimens in HER2-positive women).

Serial Monitoring of Serum Tumor Markers

Monitoring Response to Therapy

Response to systemic therapy, whether hormonal or cytotoxic, may be reflected by decreasing levels of serum tumor markers. In this setting, the value of a single tumor marker measurement, and whether it represents positive or negative response relative to an arbitrarily defined cut-off, is not as important as the trend analysis observed in serial monitoring. Interpreting trends in sequential tumor marker assays depends on understanding their normal biologic variation, as well as the analytic variability.

Monitoring for Recurrence

Patients who are no longer receiving therapy may be monitored for suspected recurrence by increasing tumor marker concentrations detected in serial monitoring. Serial monitoring of PSA in patients with a history of prostate cancer and CA-125 in patients with ovarian cancer are common examples. Limitations on interpreting results are similar to those described above for monitoring therapy response. In patients with a

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history of breast malignancy, serial monitoring for recurrence using serum tumor markers related to the MUC-1 gene (breast) has been the application most widely studied.

POLICY

A. Tumor marker CA 27.29 may be used:
   1. To monitor an already elevated titer or antigen in patients with metastatic disease.
   2. In surveillance of patients with elevated initial studies after the removal of an initial primary tumor.

B. Tumor marker CA 27.29 testing frequency:
   1. Treatment – baseline and every six weeks to assess response.
   2. Surveillance – every three months for post treatment follow-up.

RATIONALE

This policy is based on the following: one 1995 and two 1996 TEC Assessments that addressed tumor markers in breast and gastrointestinal malignancy,[1-3] a review of studies published since the TEC Assessments, and practice guidelines published by the American Society of Clinical Oncology (ASCO).[4,5] The following discussion does not address the use of CA-125, since this tumor marker is considered among the standard laboratory tests for patients with ovarian cancer.

Two key determinants of the clinical use of tumor markers are how their results will be used to affect patient management and whether the subsequent intervention will ultimately result in improved patient outcome. The application most extensively studied in breast and gastrointestinal malignancies is the use of tumor markers to monitor for recurrence. The outcomes most frequently reported are the interval between the diagnosis of metastases based on serial monitoring of tumor markers and the time at which the metastases become clinically apparent. However, these intervals may be related to both lead and length time bias and thus may have no impact on the final patient outcome of overall survival. Lead time bias refers to the fact that earlier diagnosis may not be related to improved overall survival, if there is no effective treatment. Length time bias refers to the fact that increased monitoring may primarily detect indolent, slow-growing metastases that are associated with prolonged survival regardless of treatment.

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Two randomized studies of intensive surveillance of breast cancer follow-up illustrate this point.[6,7] Both studies randomized breast cancer patients with no evidence of disease after primary treatment to receive usual care or intensive follow-up care, consisting of regularly scheduled chest x-ray and bone scan to provide early detection of the metastases in the most common sites, ie, lungs and bone. While one study reported an earlier detection of metastases in the intensively monitored group,[6] the other did not.[7] However, no difference was noted in 5-year overall survival. The lack of an improved outcome is in part related to the relatively ineffective curative treatment options for metastatic breast cancer. In this setting, quality-of-life issues related to the timing of treatment of metastatic disease may be relevant. These issues are similar to those associated with serial monitoring for recurrence of pancreatic or gastric cancer in which treatment options for recurrent disease are primarily palliative in nature.

The issues associated with serial monitoring of colorectal cancer are slightly different, since it has been shown that surgical resection of isolated liver or lung metastases may result in long-term survival in 20–30% of patients. Therefore, early diagnosis may lead to a greater incidence of detection of surgically resectable lesions. In addition, serial monitoring of serum levels of carcinoembryonic antigen (CEA) is an established practice for colorectal cancer, and thus the sensitivities and specificities of mucinous glycoprotein tumor markers must be compared to CEA, considered the gold standard. The ASCO guidelines suggest that, if resection of liver metastases would be clinically indicated, it is recommended that postoperative serum CEA testing be performed every 2–3 months in patients with stage II or III disease for 2 or more years after diagnosis.[4]

With this background in mind, the following discussion summarizes the TEC Assessments and the practice guidelines of ASCO regarding tumor markers for breast malignancies.

Breast Cancer

A 1995 TEC Assessment addressed the use of serum tumor markers in the diagnosis and monitoring of breast cancer,[1] which specifically examined the role of tumor markers as a prognostic factor in breast cancer, while a 1996 TEC Assessment focused on their use to detect recurrence.[3] These assessments provided the following observations and conclusions:

Diagnosis and Monitoring

- The evidence did not support a role for the use of serum tumor markers in the diagnosis of primary breast cancer, particularly for early stage disease, since sensitivities are low. Since none of the serum tumor markers is specific for breast cancer, they have limited utility in the differential diagnosis of metastatic disease of unknown primary. Finally, no evidence supported the use of the level of serum tumor markers as independent predictors of prognosis.
- In terms of monitoring response to therapy of metastatic disease, the serial measurement of serum tumor markers correlated well with clinical response criteria.

However, of concern was the lack of valid criteria for interpreting changes in marker levels. Criteria have been suggested, but these have not been universally accepted.

Detection of Recurrence

- The overall quality of the available studies was poor, and no studies addressed the impact of measurement of tumor markers on survival rates.
- In most studies the reported lead times (ie, difference in time of diagnosis between metastases identified with tumor marker compared to the clinical diagnosis) was 3–4 months. Whether this amount of lead time is adequate to improve therapy results is uncertain.
- One of the rationales of early identification of metastatic disease is that chemotherapy may be most effective in the setting of minimal tumor burden. However, since the level of serum tumor markers is related to tumor burden, the sensitivity of serum tumor markers falls when tumor burden is low. In addition, the false positive rate may be high; one study reported a specificity of only 60% for detection of recurrence. A high false positive rate may be associated with unnecessary additional diagnostic testing and patient anxiety.

No studies published since the 1995 TEC Assessment have addressed the above limitations. In particular, no studies have specifically examined any relationship between serial monitoring of serum tumor markers for breast cancer and the overall survival of patients, primarily related to earlier treatment of metastatic disease. Also, no studies have specifically examined the quality-of-life issues related to the timing of treatment.[7] While some studies have suggested that serum tumor markers function as prognostic factors, no trials have specifically used the results of tumor marker studies to guide treatment of the patients.[8-11] The use of tumor markers, specifically CA 15-3 or CA 27.29, may have the most value in following up response to therapy of bone metastases, which are difficult to monitor radiologically. However, no studies have validated criteria for interpreting changes in marker levels or how these criteria may be used in the management of patients.

A 2010 review article summarized the uses and limitations of CA 15-3 as a biomarker for breast cancer.[12] The article states that its main use is for monitoring therapy in patients with metastatic disease, but that it should not be used alone in this setting, but in conjunction with imaging and history and physical examination. The article suggests that the test may be most valuable for treatment monitoring in patients who have disease that cannot be evaluated using existing radiologic procedures (eg, bone metastases, ascites, pleural effusions) and that the main limitation is that serum levels are rarely increased in early or localized disease. Finally, although serial measurements of CA 15-3 in the postoperative surveillance of asymptomatic women who have undergone surgery for invasive breast cancer may provide a median lead time of 5-6 months in recurrent/metastatic cancer, it is unclear whether systemic therapy based on this lead time improves patient outcomes for survival and quality of life.

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In 2007, the American Society of Clinical Oncology (ASCO) published recommendations for the use of tumor markers in breast cancer, which were unchanged from the previously published guidelines.[5] In summary, CA 15-3 and CA 27.29 are not recommended as prognostic markers for routine clinical use because there are no trials available demonstrating a clear benefit with their use. Details of the guideline recommendations for the use of CA 15-3 and CA 27.29 are as follows: Present data are insufficient to recommend their use for screening, diagnosis, staging, or monitoring patients for recurrence after primary breast cancer therapy. For monitoring patients with metastatic disease during active therapy, CA 15-3 or CA 27.29 can be used in conjunction with diagnostic imaging, history, and physical examination. Present data are insufficient to recommend use of CA 15-3 or CA 27.29 alone for monitoring response to treatment. However, in the absence of readily measurable disease, an increasing CA 15-3 or CA 27.29 may be used to indicate treatment failure. Caution should be used when interpreting a rising CA 15-3 or CA 27.29 during the first 4-6 weeks of a new therapy, since spurious early rises may occur.

SUMMARY OF EVIDENCE

Controlled studies showing the clinical utility of the serum tumor markers addressed in this policy and improved health outcomes in patients with breast, pancreatic, gastric, or colon cancer are lacking. CA 19-9 continues to be of interest as a prognostic factor or as a monitoring tool in patients with pancreatic cancer, but no studies have shown how measurements of CA 19-9 can be used to direct management and improve patient outcomes.

PRACTICE GUIDELINES AND POSITION STATEMENT

National Comprehensive Cancer Network (NCCN) Guidelines

NCCN guidelines for breast cancer (v1.2019) state that rising tumor markers (eg, CEA, CA15-3, CA27.29) are concerning for tumor progression, but may also be seen in the setting of responding disease. An isolated increase in tumor markers should rarely be used to declare progression of disease. Changes in bone lesions are often difficult to assess on plain or cross-sectional radiology or on bone scan. For these reasons, patient symptoms and serum tumor markers may be more helpful in patients with bone-dominant metastatic disease.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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CPT/HCPCS

86300	Immunoassay for tumor antigen, quantitative; CA 15-3 (27.29)

ICD-10 Diagnoses

C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast

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Z85.3 Personal history of malignant neoplasm of breast

REVISIONS

07-13-2003	Deleted old policy and added new policy.
03-27-2014	Title changed from: "Tumor Markers CA-15-3 and CA-27.29" to " Serum Tumor Markers for Breast and Gastrointestinal Malignancies"
	Updated Description section.
	Added Medical Policy and Coding Disclaimers
	In Policy section: ▪ Removed "Tumor marker CA 27.29 will not be used: for screening patients who have not been proven to have breast cancer." ▪ Removed "Tumor marker CA 27.29 is a superior test to CA-15-3 and therefore CA-15-3 should be used." ▪ Inserted "Tumor markers CA-15-3 & CA 27.29 are considered experimental / investigational as a technique to diagnose, determine prognosis, select therapy, assess response to therapy or monitor for reoccurrence of gastrointestinal malignancies. Gastrointestinal malignancies include gastric, pancreatic, and colorectal cancer." ▪ Formatted policy language. ▪ Removed Utilization section.
	Added Rationale section.
	In Coding section: ▪ Updated nomenclature ▪ Added ICD-10 Diagnosis *(Effective October 1, 2014)*
	Updated Reference section.
03-18-2015	Title of policy changed from "Serum Tumor Markers for Breast and Gastrointestinal Malignancies"
	Updated Description section.
	In Policy section: ▪ Removed Item C, "Tumor markers CA -15-3 and CA 27.29 are considered experimental / investigational as a technique to diagnose, determine prognosis, select therapy, assess response to therapy or monitor for reoccurrence of gastrointestinal malignancies. Gastrointestinal malignancies include gastric, pancreatic, and colorectal cancer."
	Updated Rationale section.
03-02-2016	Updated Rationale section.
	Updated References section.
01-18-2017	Updated Rationale section.
	Updated References section.
	Remainder of policy reviewed; no other revisions made.
02-15-2018	In Coding section: ▪ Removed ICD-9 codes.

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	Updated References section.
	Remainder of the policy was reviewed; no other revisions made.
04-24-2019	Updated Rationale section.
	Updated References section.

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