Medical Coverage Policy | Serum Tumor Markers for Breast and Gastrointestinal Malignancies

EFFECTIVE DATE: 09|26|2003
POLICY LAST UPDATED: 09|19|2017

OVERVIEW
This policy addresses the coverage for tumor markers only when utilized for the management of cancerous conditions. Tumor markers are substances produced in low quantities by tumor cells or other cells of the body in response to the presence of cancer or certain benign conditions. This policy addresses the tumor antigens: CA 15-3, 27.29, and CA-19. CA 15-3 and CA 27.29 (Truquant RIA is equivalent to CA 15-3) are used to assist in the management of individuals with breast cancer or for a breast mass of unspecified or uncertain behavior. CA 19-9 is used to monitor patients for clinical response to therapy or to detect recurrent pancreatic and biliary ductal carcinoma following surgery and/or chemotherapy.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
The noted immunoassay tests for tumor antigens CA 15-3 (CA 27.29) or CA 19-9 are medically necessary when filed with a covered diagnosis.

All other indications are considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND
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. Examples of the latter include the HER2 oncoprotein, detected by immunohistochemistry 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 (i.e., β2-microglobulin), germ cell tumors (i.e., alpha fetoprotein, human chorionic gonadotropin), and prostate cancer (i.e., 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 and gastrointestinal malignancies.

For breast cancer, the most extensively investigated serum tumor markers besides HER2 are those associated with the MUC-1 gene. For gastrointestinal cancer, including gastric, pancreatic, and colorectal cancer, the most extensively studied tumor markers, other than CEA, are those related to mucinous glycoproteins. 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 two 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. The mucinous glycoproteins of the gastrointestinal tract include CA 19-9, and CA 72-4, depending on which antibody is used.

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 cutoff 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.

CODING

BlueCHiP for Medicare and Commercial Products

The following immunoassay tests are considered **medically necessary** with one of the indicated diagnosis codes below:

86300 Immunoassay for tumor antigen, quantitative; CA 15-3 (CA 27.29)
86301 Immunoassay for tumor antigen, quantitative; CA 19-9

The following immunoassay test is considered **not medically necessary**:

86316 Immunoassay for tumor antigen, other antigen, quantitative (eg, CA 50, 72-4, 549), each

Diagnosis codes covered for CPT code 86300**:**

ICD10codes86300.pdf

Diagnosis codes covered for CPT code 86301:

ICD10Codes86301.pdf

RELATED POLICIES

CA 125
Serum Biomarker Human Epididymis Protein 4
BlueCHiP for Medicare National and Local Coverage Determinations Policy

PUBLISHED

Provider Update, November 2017
Provider Update, February 2017
Provider Update, May 2016
Provider Update, December 2014
Provider Update, July 2013
Provider Update, February 2012
Provider Update, April 2011

Provider Update, October 2009

REFERENCES

1. Centers for Medicare and Medicaid Services. NCD for Tumor Antigen by Immunoassay - CA 15-3/CA 27.29 (190.29). https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=134&ncdver=1&DocID=190.29&bc=gAAAABAAAAAAAA%3d%3d&

2. Centers for Medicare and Medicaid Services. NCD for Tumor Antigen by IMMUNOASSAY - CA 19-9 (190.30). https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=142&ncdver=1&DocID=190.30&bc=gAAAABAAAAAAAA%3d%3d&

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