

Medical Coverage Policy



Immunoassay for Tumor Antigens (Tumor Markers)

Device/Equipment Drug Medical Surgery Test Other

Effective Date:	7/1/2011	Policy Last Updated:	12/6/2011
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Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

This policy addresses tumor markers only when utilized for the management of cancerous conditions.

Description:

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. Tumor-associated antigen immunological tests measure the tumor-associated antigens in serum, plasma, urine, or other body fluids. Detection of a higher-than-normal serum level by radioimmunoassay or immunohistochemical methods usually indicates the tumor marker levels are beneficial in the detection, diagnosis, and treatment of some types of cancer. However, measurement of tumor marker levels alone is not sufficient to diagnose cancer, as tumor marker levels may be elevated in persons with benign conditions. Levels are not elevated in every person with cancer, especially in the early stage of the disease. Many tumor markers are not specific to a particular type of cancer and may be elevated by more than one type of cancer. With the exception of prostate-specific antigen (PSA), tumor markers do not have sufficient sensitivity or specificity for use in screening.

Tumor marker levels are also measured before treatment to help doctors plan the most appropriate treatment therapies. In some types of cancer, tumor marker levels can be used to stage disease and to predict how well the disease will respond to treatment. Levels may also be measured to assess patient response to treatment. Tumor marker levels may also be used to check for disease recurrence after the conclusion of treatment.

Human Epididymis Protein 4 (HE4)

Human Epididymis Protein 4 (HE4) is a potential new biomarker for detecting ovarian cancer early and for monitoring disease progression and recurrence. It has been cleared by the FDA for monitoring patients with epithelial ovarian cancer. HE4 is proposed as a replacement for or complement to CA-125, a biomarker with limited specificity.

There are limited data on the diagnostic test performance of the HE4 test used to monitor disease progression and recurrence in women diagnosed with epithelial ovarian cancer. Reported studies are small, retrospective with possible duplicate data on the same women. In

general, there is no established cut-off for determining when an HE4 test is positive, whether for identifying disease progression or recurrence, or for determining risk of malignancy in women with adnexal masses. No further validation studies have been published. In addition, no data are available from prospective studies on the clinical utility of any application of the HE4 test and there are no published studies on use of the HE4 test to screen asymptomatic women. Thus, the HE4 test is considered not medically necessary for all indications.

Medical Criteria:

The following tumor antigens and their associated indications and diagnoses are considered **medically necessary**.

- **BTA Stat Test (Bladder tumor antigen) (CPT code 86294)** is used as an adjunct in the initial diagnosis of patients with a suspected bladder cancer and to monitor for eradication of the cancer, or recurrences after eradication.
Diagnosis codes: 188.0-188.9, 198.1, 199.1, 233.7, 239.4, 599.70, 599.71, 599.72, 724.2, 788.1, 788.33, 788.41-788.43, 788.91, V10.51, V16.8
- **NMP 22 (Nuclear Matrix protein) (CPT code 86294, 86386 covered effective 1/1/12)** is used as an adjunct in the diagnosis and monitoring of bladder cancer.
Diagnosis codes: 188.0-188.9, 198.1, 199.1, 233.7, 239.4, 599.70, 599.71, 599.72, 724.2, 788.1, 788.33, 788.41-788.43, 788.91, V10.51, V16.8
- **CA 15-3 (CPT code 86300) (CA 27.29 [CPT code 86300])** or Truquant RIA is equivalent to **CA 15-3** is used to assist in the management of individuals with breast cancer. It is also used when a breast mass of unspecified or uncertain behavior is present.
Diagnosis codes: 174.0-174.9, 175.0- 175.9, 198.2 198.81, 199.1, 338.3, 795.89, 611.72, V10.3, V71.1
- **CA 19-9 (CPT code 86301)** is used to monitor patients for clinical response to therapy or to detect recurrent pancreatic and biliary ductal carcinoma following surgery and/or chemotherapy.
Diagnosis codes: 155.1, 156.0, 156.1, 156.2, 156.8, 156.9, 157.0-157.9, 197.8, 199.1, 235.3, 235.5, 338.3, 795.89, V10.09.
- **CA 125 (CPT code 86304)** levels for any of the following:
 - In detecting suspicious gynecological cancers such as epithelial ovarian, fallopian tube, endometrium and endocervix carcinomas.
 - In detecting suspicious symptoms suggestive of malignant mesothelioma or primary peritoneal carcinoma.
 - In detecting a suspicious pelvic mass preparatively and as a baseline for post-operative monitoring.
 - In the management and treatment of ovarian cancer after initial surgery and/or chemotherapy.
 - In monitoring advanced or recurrent disease response after therapy.**Diagnosis codes:** 158.0, 158.8, 158.9, 180.0, 182.0, 183.0-183.9, 184.8, 198.6, 198.82, 199.0, 199.1, 236.0-236.3, 338.3, 789.30-789.39, 795.82, 795.89, V10.41, V10.42, V10.43, V10.44, V71.1

Human Epididymis Protein 4 (HE4) is considered **not medically necessary** for the diagnosing, monitoring and screening of ovarian cancer as there are no prospective studies comparing

health outcomes in patients managed with and without HE4 testing, alone or in combination with other disease markers. **(Effective 7/1/2011)**

All other uses for BTA Stat Test, NMP 22, CA 15-3, CA 27.29, CA 19-9 or CA 125 not mentioned above are considered **not medically necessary**.

All other tumor markers are considered **not medically necessary**.

Policy:

The above-noted immunoassay tests for tumor antigens with their associated indications and diagnosis are considered **medically necessary**. There are no limits to the number of tests an individual can have.

Immunoassay tests when used for screening of asymptomatic persons are considered **not medically necessary**, as literature does not support its efficacy.

Prior authorization is not required

Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for the applicable diagnostic imaging, lab and machine tests benefits.

Coding and Reimbursement:

The following immunoassay tests are considered **medically necessary**:

86294

86300

86301

86304

86386 Effective 1/1/2012

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

86305

86316

Also known as:

Not applicable

Related Topics:

Not applicable

Published:

Policy Update, November 2007

Policy Update, July 2008

Provider Update, October 2009

Provider Update, April 2011

Provider Update, February 2012

References:

Blue Cross and Blue Shield Association: 2.04.07 Urinary Tumor Markers for Bladder Cancer. retrieved 4/28/09, 9/13/2010, 11/16/11:

http://blueweb.bcbs.com/global_assets/special_content/medical_policy/policymanual/policy.html?pnum=20407.

Blue Cross and Blue Shield Association: 2.03.02 Serum Tumor Markers for Breast and Gastrointestinal Malignancies. retrieved 4/28/09 and 9/13/2010, 11/16/2011

http://blueweb.bcbs.com/global_assets/special_content/medical_policy/policymanual/policy.html?pnum=20302

Blue Cross and Blue Shield Association: 2.04.27 CA-125. Retrieved 9/20/2010

Blue Cross and Blue Shield Association: 2.04.66 Serum Biomarker Human Epididymis Protein 4 (HE4). Retrieved 9/20/2010, 11/16/2011.

Centers for Medicare and Medicaid Services. NCD for Tumor Antigen by IMMUNOASSAY - CA 125 (190.28). Retrieved 4/28/09, 11/16/11:

<http://www.cms.hhs.gov/Transmittals/Downloads/R47NCD.pdf>.

Centers for Medicare and Medicaid Services. NCD for Tumor Antigen by Immunoassay - CA 15-3/CA 27.29 (190.29). Retrieved 11/16/2011

4/28/09:http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=190.29&ncd_version=1&basket=ncd%3A190%2E29%3A1%3ATumor+Antigen+by+Immunoassay+%2D+CA+15%2D3%2FCA+27%2E29.

Centers for Medicare and Medicaid Services. NCD for Tumor Antigen by IMMUNOASSAY - CA 19-9 (190.30). Retrieved 4/28/09, 11/16/11:

http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=190.30&ncd_version=1&basket=ncd%3A190%2E30%3A1%3ATumor+Antigen+by+Immunoassay+%2D+CA+19%2D9.

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