

Medical Coverage Policy



**Blue Cross
Blue Shield**
of Rhode Island

Immunoassay for Tumor Antigens

Device/Equipment Drug Medical Surgery Test Other

Effective Date:	7/1/2011	Policy Last Updated:	5/7/2013
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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 specific 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 for the indicated conditions and diagnoses are considered medically necessary for all BCBSRI products.

- CA 15-3, CA 27.29 (Truquant RIA is equivalent to CA 15-3) used to assist in the management of individuals with breast cancer or for a breast mass of unspecified or uncertain behavior.
- CA 19-9 used to monitor patients for clinical response to therapy or to detect recurrent pancreatic and biliary ductal carcinoma following surgery and/or chemotherapy.
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- CA 125 used for any of the following indications:
 - 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 preoperatively 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.

Human Epididymis Protein 4 (HE4) is considered not medically necessary for all indications as there is insufficient evidence to support its efficacy.

All other tumor markers not listed in the criteria above are considered not medically necessary as there is insufficient evidence to support their efficacy.

Policy:

Prior authorization is not required

The above noted immunoassay tests for tumor antigens with their associated indications and diagnosis (see Coding and reimbursement below) are considered **medically necessary**. There are no limits to the number of tests an individual may have.

Immunoassay tests for the screening of individuals who are asymptomatic are considered not medically necessary as literature does not support its efficacy.

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** for one of the indicated diagnosis codes below for all BCBSRI products:

86300

86301

86304

The following immunoassay tests are considered **not medically necessary**:

86305

86316

The following CPT code is considered **medically necessary** for one of the indicated diagnosis codes below:

86300

ICD-9-CM

174.0	174.1	174.2	174.3	174.4	174.5	174.6	174.8	174.9	175.0
175.9	198.2	198.81	199.1	338.3	611.72	795.89	V10.3	V71.1	

ICD-10-CM

C50.011	C50.119	C50.212	C50.319	C50.419	C50.511	C50.619
C50.812	C50.911	C50.022	C50.122	C79.2	C79.81	C45.9
G89.3	N63	R97.8	Z85.3	Z03.89		

The following CPT code is considered **medically necessary** for one of the indicated diagnosis codes below:

86301

ICD-9-CM

155.1	156.0	156.1	156.2	156.8	156.9	157.0	157.1	157.2	157.3
157.4	157.8	157.9	197.8	199.1	235.3	235.5	338.3	795.89	V10.09

ICD-10-CM

C22.1	C23	C24.0	C24.1	C24.8	C24.9	C25.0	C25.1	C25.2	C25.3
C25.4	C25.7	C25.9	C78.89	C45.9	D37.6	D37.9	G89.3	R97.8	Z85.068

The following CPT code is considered **medically necessary** for one of the indicated diagnosis codes below:

86304

ICD-9-CM

158.0	158.8	158.9	180.0	182.0	183.0	183.2	183.3	183.4	183.5
183.8	184.8	198.6	198.82	199.0	199.1	236.0	236.1	236.2	236.3
338.3	789.30	789.31	789.32	789.33	789.34	789.35	789.36	789.37	789.39
795.82	795.89	V10.41	V10.42	V10.43	V10.44	V71.1			

ICD-10-CM

C48.0	C45.1	C48.1	C48.8	C48.2	C53.0	C54.1	C54.3	C54.9	C54.2
C56.1	C56.9	C57.02	C57.01	C57.00	C57.11	C57.12	C57.10	C57.3	C57.22
C57.20	C57.21	C57.4	C57.7	C57.8	C51.8	C79.61	C79.60	C79.62	C79.82
C80.0	C45.9	C80.1	G73.1	D39.0	D39.2	D39.12	D39.11	D39.10	D39.9
G89.3	R19.00	R19.01	R19.02	R19.03	R19.04	R19.05	R19.06	R19.07	R19.09
R97.1	R97.8	Z85.41	Z85.42	Z85.43	Z85.44	Z03.89			

Also known as:

CA 15-3
CA 19-9
CA 125

Related Topics:

Proteomics-based Testing for the Evaluation of Ovarian (Adnexal) Masses [Notes Link](#)

Published:

Provider Update, July 2013
Provider Update, February 2012
Provider Update, October 2009
Provider Update, April 2011
Policy Update, July 2008
Policy Update, November 2007

References:

Blue Cross and Blue Shield Association: Serum Biomarker Human Epididymis Protein 4 (HE4).

Blue Cross and Blue Shield Association: 2.04.07 Urinary Tumor Markers for Bladder Cancer.

Blue Cross and Blue Shield Association: 2.03.02 Serum Tumor Markers for Breast and Gastrointestinal Malignancies

Centers for Medicare and Medicaid Services. NCD for Tumor Antigen by IMMUNOASSAY - CA 125 (190.28). <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).

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).

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.

Review History:

05/07/2013: Annual review of the policy.

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