**EFFECTIVE DATE:** 10/07/2014
**POLICY LAST UPDATED:** 10/07/2014

## 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.

## PRIOR AUTHORIZATION

Prior Authorization is not required

## POLICY STATEMENT

**BlueCHiP for Medicare and Commercial**

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

## 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.

- **CA 125** used for any of the following indications:

  **Note**: The following guidelines are not applicable for a simple ovarian cyst

  - In detecting suspicious gynecological cancers such as epithelial ovarian, fallopian tube, endometrium and endocervix carcinomas or a complex ovarian cyst.
  - 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.

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.**

## BACKGROUND

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 maker 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.

## COVERAGE

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

## CODING

**BlueCHiP for Medicare and Commercial**

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

| | | |
|---|---|---|
| **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 Codes: | | | | | | |
| 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 Codes: | | | | | | |
| 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 Codes: | | | | | | |
| 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 Codes: | | | | | | |
| C22.1 | C23 | C24.0 | C24.1 | C24.8 | C24.9 | C25.0 |
| C25.4 | C25.7 | C25.9 | C78.89 | C45.9 | D37.6 | D37.9 |
| G89.3 | R97.8 | Z85.068 | C25.1 | C25.2 | C25.3 | |
| The following CPT code is considered **medically necessary** for one of the indicated diagnosis codes below: **86304** | | | | | | |
| 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 |
| 620.2 | 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 Codes: | | | | | | |
| C48.0 | C45.1 | C48.1 | C48.8 | C48.2 | C53.0 | C54.1 |
| C54.3 | C54.9 | C54.2 | C56.1 | C56.2 | C56.9 | C57.00 |
| C57.01 | C57.11 | C57.12 | C57.10 | C57.3 | C57.22 | C57.20 |
| C57.02 | C57.4 | C57.7 | C57.8 | C51.8 | C79.60 | C79.61 |
| C79.62 | C79.82 | C80.0 | C45.9 | C80.1 | G73.1 | D39.0 |
| D39.12 | D39.2 | D39.11 | D39.10 | D39.9 | G89.3 | N83.20 |
| N83.29 | 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 | | | | |

## RELATED POLICIES

None

## PUBLISHED

| | |
|---|---|
| Provider Update | Dec 2014 |
| Provider Update | Jul 2013 |
| Provider Update | Feb 2012 |
| Provider Update | Apr 2011 |

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|---|---|
| Provider Update | Oct 2009 |
| Provider Update | Jul 2008 |
| Provider Update | Nov 2007 |

## REFERENCES


1. Centers for Medicare and Medicaid Services. NCD for Tumor Antigen by IMMUNOASSAY - CA 125 (190.28) http://www.cms.hhs.gov/Transmittals/Downlo.ads/R47NCD.pdf

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

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


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