



## Medical Policy

### CA 125

#### Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)
- [Endnotes](#)

#### Policy Number: 503

BCBSA Reference Number: 2.04.27A

NCD/LCD: National Coverage Determination (NCD) for Tumor Antigen by Immunoassay - CA 125 (190.28)

#### Related Policies

Serum Biomarker Human Epididymis Protein 4 (HE4) #[290](#)

Tumor Markers for Diagnosis and Management of Cancer #[167](#)

#### Policy<sup>1</sup>

##### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Measurements of CA-125 may be considered **MEDICALLY NECESSARY** in patients with symptoms suggestive of ovarian cancer or in those with known ovarian cancer, to aid in the monitoring of disease, response to treatment, and recurrence of disease (including assessing value of second-look surgery).

Measurements of CA-125 may be considered **MEDICALLY NECESSARY** in individual patients with other gynecologic malignancies, such as endometrial cancer, in whom baseline levels of CA-125 have been shown to be elevated.

Measurements of CA-125 may be considered **MEDICALLY NECESSARY** in patients with pelvic mass with unknown diagnosis.

Measurements of CA-125 may be considered **MEDICALLY NECESSARY** in peritoneal primary cancer to aid in monitoring of disease.

Measurements of CA-125 may be considered **MEDICALLY NECESSARY** in patients with adenocarcinoma of unknown primary (abdominal or pelvic carcinomatosis).

Measurements of CA-125 may be considered **MEDICALLY NECESSARY** as an indicator of tumor size or grade for lung cancer.

Measurements of CA-125 are considered **INVESTIGATIONAL** in asymptomatic patients as a screening technique for ovarian cancer.

Measurements of CA-125 are considered **INVESTIGATIONAL** in colorectal, gastric, liver, or pancreatic cancer diagnosis, monitoring or prognosis.

## Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

### Indications

CA 125 is a high molecular weight serum tumor marker elevated in 80% of patients who present with epithelial ovarian carcinoma. It is also elevated in carcinomas of the fallopian tube, endometrium, and endocervix. An elevated level may also be associated with the presence of a malignant mesothelioma or primary peritoneal carcinoma.

A CA125 level may be obtained as part of the initial pre-operative work-up for women presenting with a suspicious pelvic mass to be used as a baseline for purposes of post-operative monitoring. Initial declines in CA 125 after initial surgery and/or chemotherapy for ovarian carcinoma are also measured by obtaining three serum levels during the first month post treatment to determine the patient's CA 125 half-life, which has significant prognostic implications.

The CA 125 levels are again obtained at the completion of chemotherapy as an index of residual disease. Surveillance CA125 measurements are generally obtained every 3 months for 2 years, every 6 months for the next 3 years and yearly thereafter. CA 125 levels are also an important indicator of a patient's response to therapy in the presence of advanced or recurrent disease. In this setting, CA 125 levels may be obtained prior to each treatment cycle.

### Limitations

These services are not covered for the evaluation of patients with signs or symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

The CA 125 is specifically not covered for aiding in the differential diagnosis of patients with a pelvic mass as the sensitivity and specificity of the test is not sufficient. In general, a single "tumor marker" will suffice in following a patient with one of these malignancies.

### National Coverage Determination (NCD) for Tumor Antigen by Immunoassay - CA 125 (190.28)

<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=130&ncdver=2&bc=BAIAAAAAAAAA&>

### Prior Authorization Information

Pre-service approval is required for all inpatient services for all products.

See below for situations where prior authorization may be required or may not be required.

Yes indicates that prior authorization is required.

No indicates that prior authorization is not required.

N/A indicates that this service is primarily performed in an inpatient setting.

	Outpatient
Commercial Managed Care (HMO and POS)	No
Commercial PPO and Indemnity	No
Medicare HMO Blue <sup>SM</sup>	No
Medicare PPO Blue <sup>SM</sup>	No

### CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code 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 as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

The above **medical necessity criteria** **MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

**CPT Codes**

CPT codes:	Code Description
86304	Immunoassay for tumor antigen, quantitative; CA 125

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if **medical necessity criteria** are met:

**ICD-9 Diagnosis Codes**

ICD-9-CM diagnosis codes:	Code Description
158.8	Malignant neoplasm of specified parts of peritoneum
158.9	Malignant neoplasm of peritoneum, unspecified
159.8	Malignant neoplasm of other sites of digestive system and intra-abdominal organs
162.2	Malignant neoplasm of main bronchus
162.3	Malignant neoplasm of upper lobe, bronchus, or lung
162.4	Malignant neoplasm of middle lobe, bronchus, or lung
162.5	Malignant neoplasm of lower lobe, bronchus, or lung
162.8	Malignant neoplasm of other parts of bronchus or lung
162.9	Malignant neoplasm of bronchus and lung, unspecified site
171.5	Malignant neoplasm of connective and other soft tissue of abdomen
182.0	Malignant neoplasm of corpus uteri, except isthmus
183.0	Malignant neoplasm of ovary
183.2	Malignant neoplasm of fallopian tube
183.3	Malignant neoplasm of broad ligament of uterus
183.4	Malignant neoplasm of parametrium of uterus
183.5	Malignant neoplasm of round ligament of uterus
183.8	Malignant neoplasm of other specified sites of uterine adnexa
183.9	Malignant neoplasm of uterine adnexa, unspecified site
195.2	Malignant neoplasm of abdomen
195.3	Malignant neoplasm of pelvis
196.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
196.6	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
196.9	Secondary and unspecified malignant neoplasm of lymph nodes, site unspecified
197.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
198.6	Secondary malignant neoplasm of ovary
198.82	Secondary malignant neoplasm of genital organs
233.2	Carcinoma in situ of other and unspecified parts of uterus
233.30	Carcinoma in situ, unspecified female genital organ
233.31	Carcinoma in situ, vagina
233.32	Carcinoma in situ, vulva
233.39	Carcinoma in situ, other female genital organ
235.4	Neoplasm of uncertain behavior of retroperitoneum and peritoneum
236.0	Neoplasm of uncertain behavior of uterus
236.2	Neoplasm of uncertain behavior of ovary
239.5	Neoplasm of unspecified nature of other genitourinary organs
789.30	Abdominal or pelvic swelling, mass or lump, unspecified site
789.31	Abdominal or pelvic swelling, mass, or lump, right upper quadrant
789.32	Abdominal or pelvic swelling, mass, or lump, left upper quadrant
789.33	Abdominal or pelvic swelling, mass, or lump, right lower quadrant

789.34	Abdominal or pelvic swelling, mass, or lump, left lower quadrant
789.35	Abdominal or pelvic swelling, mass or lump, periumbilic
789.36	Abdominal or pelvic swelling, mass, or lump, epigastric
789.37	Abdominal or pelvic swelling, mass, or lump, generalized
789.39	Abdominal or pelvic swelling, mass, or lump, other specified site

## ICD-10 Diagnosis Codes

<b>ICD-10-CM diagnosis codes:</b>	<b>Code Description</b>
C26.9	Malignant Neoplasm Of Ill-Defined Sites Within The Digestive System
C34.00	Malignant Neoplasm Of Unspecified Main Bronchus
C34.01	Malignant Neoplasm Of Right Main Bronchus
C34.02	Malignant Neoplasm Of Left Main Bronchus
C34.10	Malignant Neoplasm Of Upper Lobe, Unspecified Bronchus Or Lung
C34.11	Malignant Neoplasm Of Upper Lobe, Right Bronchus Or Lung
C34.12	Malignant Neoplasm Of Upper Lobe, Left Bronchus Or Lung
C34.30	Malignant Neoplasm Of Lower Lobe, Unspecified Bronchus Or Lung
C34.31	Malignant Neoplasm Of Lower Lobe, Right Bronchus Or Lung
C34.32	Malignant Neoplasm Of Lower Lobe, Left Bronchus Or Lung
C34.80	Malignant Neoplasm Of Overlapping Sites Of Unspecified Bronchus And Lung
C34.81	Malignant Neoplasm Of Overlapping Sites Of Right Bronchus And Lung
C34.82	Malignant Neoplasm Of Overlapping Sites Of Left Bronchus And Lung
C34.90	Malignant Neoplasm Of Unspecified Part Of Unspecified Bronchus Or Lung
C34.91	Malignant Neoplasm Of Unspecified Part Of Right Bronchus Or Lung
C34.92	Malignant Neoplasm Of Unspecified Part Of Left Bronchus Or Lung
C45.1	Mesothelioma Of Peritoneum
C47.4	Malignant Neoplasm Of Peripheral Nerves Of Abdomen
C48.1	Malignant Neoplasm Of Specified Parts Of Peritoneum
C48.2	Malignant Neoplasm Of Peritoneum, Unspecified
C48.8	Malignant Neoplasm Of Overlapping Sites Of Retroperitoneum And Peritoneum
C49.4	Malignant Neoplasm Of Connective And Soft Tissue Of Abdomen
C54.1	Malignant Neoplasm Of Endometrium
C54.2	Malignant Neoplasm Of Myometrium
C54.3	Malignant Neoplasm Of Fundus Uteri
C54.9	Malignant Neoplasm Of Corpus Uteri, Unspecified
C56.1	Malignant Neoplasm Of Right Ovary
C56.2	Malignant Neoplasm Of Left Ovary
C56.9	Malignant Neoplasm Of Unspecified Ovary
C57.00	Malignant Neoplasm Of Unspecified Fallopian Tube
C57.01	Malignant Neoplasm Of Right Fallopian Tube
C57.02	Malignant Neoplasm Of Left Fallopian Tube
C57.10	Malignant Neoplasm Of Unspecified Broad Ligament
C57.11	Malignant Neoplasm Of Right Broad Ligament
C57.12	Malignant Neoplasm Of Left Broad Ligament
C57.20	Malignant Neoplasm Of Unspecified Round Ligament
C57.21	Malignant Neoplasm Of Right Round Ligament
C57.22	Malignant Neoplasm Of Left Round Ligament
C57.3	Malignant Neoplasm Of Parametrium
C57.4	Malignant Neoplasm Of Uterine Adnexa, Unspecified
C76.2	Malignant Neoplasm Of Abdomen
C76.3	Malignant neoplasm of pelvis
C77.2	Secondary And Unspecified Malignant Neoplasm Of Intra-Abdominal Lymph Nodes

C77.5	Secondary And Unspecified Malignant Neoplasm Of Intrapelvic Lymph Nodes
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C79.60	Secondary Malignant Neoplasm Of Unspecified Ovary
C79.61	Secondary Malignant Neoplasm Of Right Ovary
C79.62	Secondary Malignant Neoplasm Of Left Ovary
C79.82	Secondary Malignant Neoplasm Of Genital Organs
D07.0	Carcinoma In Situ Of Endometrium
D07.1	Carcinoma In Situ Of Vulva
D07.2	Carcinoma In Situ Of Vagina
D07.30	Carcinoma In Situ Of Unspecified Female Genital Organs
D07.39	Carcinoma In Situ Of Other Female Genital Organs
D39.0	Neoplasm Of Uncertain Behavior Of Uterus
D39.10	Neoplasm Of Uncertain Behavior Of Unspecified Ovary
D39.11	Neoplasm Of Uncertain Behavior Of Right Ovary
D39.12	Neoplasm Of Uncertain Behavior Of Left Ovary
D48.4	Neoplasm Of Uncertain Behavior Of Peritoneum
D49.5	Neoplasm Of Unspecified Behavior Of Other Genitourinary Organs
D49.59	Neoplasm unspecified behavior of other genitourinary organ
R19.00	Intra-Abdominal And Pelvic Swelling, Mass And Lump, Unspecified Site
R19.01	Right Upper Quadrant Abdominal Swelling, Mass And Lump
R19.02	Left Upper Quadrant Abdominal Swelling, Mass And Lump
R19.03	Right Lower Quadrant Abdominal Swelling, Mass And Lump
R19.04	Left Lower Quadrant Abdominal Swelling, Mass And Lump
R19.05	Periumbilic Swelling, Mass Or Lump
R19.06	Epigastric Swelling, Mass Or Lump
R19.07	Generalized Intra-Abdominal And Pelvic Swelling, Mass And Lump
R19.09	Other Intra-Abdominal And Pelvic Swelling, Mass And Lump

## Description

CA-125 is an accepted tool for monitoring patients with known ovarian cancer and other gynecologic malignancies. It has been proposed for use as a screening test in asymptomatic women.

CA-125 is a high-molecular-weight protein antigen that is commonly elevated in patients with known ovarian cancer. CA-125 may also be elevated in other gynecologic malignancies, such as endometrial cancer, although the association is not as consistent as that with ovarian cancer. CA-125 has been widely used as a technique to monitor patients with known ovarian cancer or other gynecologic malignancies that, in individual patients, are associated with elevated levels of CA-125. Frequently, a rising CA-125 will be the initial sign of recurrent disease.

CA-125 has also been investigated as a possible screening tool for ovarian cancer, both in the general population and in patients considered at high risk of ovarian cancer.

Levels of CA-125 may also be elevated in nonmalignant conditions, including pregnancy, endometriosis, pelvic inflammatory disease, benign ovarian masses, and without any identifiable cause.

## Policy History

Date	Action
10/2016	Clarified coding information.
11/2015	Ongoing medically necessary and investigational statements transferred from medical policy #167 Tumor Markers for Diagnosis and Management of Cancer. Clarified coding information. 11/1/2015
1/2015	Clarified coding information.
6/2014	Updated coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
4/2014	Clarified coding information.

6/2012	Updated with additional references based on BCBSA national policy reviewed 10/2011.
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## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

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4. United Kingdom Collaborative Trial of Ovarian Cancer Screening. Available online at: [http://www.instituteforwomenshealth.ucl.ac.uk/academic\\_research/gynaecologicalcancer/gcrc/ukctocs](http://www.instituteforwomenshealth.ucl.ac.uk/academic_research/gynaecologicalcancer/gcrc/ukctocs) Last accessed September 2011
5. National Comprehensive Cancer Network. Ovarian Cancer. Clinical practice guidelines in oncology, v2.2011. Available online at: [http://www.nccn.org/professionals/physician\\_gls/PDF/ovarian.pdf](http://www.nccn.org/professionals/physician_gls/PDF/ovarian.pdf). Last accessed September 2011.
6. U.S. Preventive Services Task Force. Screening for Ovarian Cancer: Recommendation Statement. May 2004. Available online at: <http://www.uspreventiveservicestaskforce.org/3rduspstf/ovariancan/ovcanrs.htm>. Last accessed August 2011.
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8. Society of Gynecologic Oncologists Statement Regarding OvaSure™ available at <http://www.sgo.org/WorkArea/showcontent.aspx?id=1846>. FDA letter to the manufacturer, August 7, 2008

## Endnotes

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<sup>1</sup> Based on expert opinion and MPRM 2.04.27A