

Medical Policy CA 125

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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

Policy¹

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 <u>MEDICALLY NECESSARY</u> 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 <u>MEDICALLY NECESSARY</u> in patients with pelvic mass with unknown diagnosis.

Measurements of CA-125 may be considered <u>MEDICALLY NECESSARY</u> in peritoneal primary cancer to aid in monitoring of disease.

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

Measurements of CA-125 may be considered <u>MEDICALLY NECESSARY</u> 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 BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance can be found through the link(s) below.

National Coverage Determinations (NCDs)

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

Note: To review the specific NCD, please remember to click "accept" on the CMS licensing agreement at the bottom of the CMS webpage.

Prior Authorization Information

Inpatient

For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

Outpatient

 For services described in this policy, see below for products where prior authorization <u>might be required</u> if the procedure is performed <u>outpatient</u>.

| | Outpatient |
|---------------------------------------|--|
| Commercial Managed Care (HMO and POS) | Prior authorization is not required . |
| Commercial PPO and Indemnity | Prior authorization is not required . |
| Medicare HMO Blue sM | Prior authorization is not required . |
| Medicare PPO Blue SM | Prior authorization is not required . |

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 noncoverage 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 <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

| Code Description |
|---|
| Immunoassay for tumor antigen, quantitative; CA 125 |
| |

ICD-10 Diagnosis Codes

| ICD-10-CM diagnosis | |
|------------------------|---|
| codes: | Code Description |
| C26.9 | Malignant Neoplasm of III-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 |
| C34.80 | Malignant Neoplasm of Overlapping Sites of Right Bronchus and Lung |
| C34.81 | Malignant Neoplasm of Overlapping Sites of Nght Bronchus and Lung |
| | Malignant Neoplasm of Unspecified Part of Unspecified Bronchus or Lung |
| C34.90 | Malignant Neoplasm of Unspecified Part of Right Bronchus or Lung |
| C34.91 | |
| 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.

| Date | Action |
|---------|---|
| 11/2019 | ICD-9 codes removed. |
| 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. |
| 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. |

Policy History

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

- Buys SS, Partridge E, Black A et al. for the PLCO team. Effect of screening on ovarian cancer mortality: The prostate, lung, colorectal and ovarian (PLCO) cancer screening randomized controlled trial. JAMA 2011; 305: 2295-2303.
- 2. Jacobs IJ, Skates SJ, MacDonald N et al. Screening of ovarian cancer: a pilot randomized controlled trial. Lancet 1999; 353(9160): 1207-10.
- 3. Burke W. Daly M. Garber J et al. Recommendations for follow-up care of individuals with an inherited predisposition to cancer. II. BRCA1 and BRCA2. JAMA 1997; 277(12): 997-1003.

- 4. United Kingdom Collaborative Trial of Ovarian Cancer Screening. Available online at: <u>http://www.instituteforwomenshealth.ucl.ac.uk/academic_research/gynaecologicalcancer/gcrc/ukctocs Last</u> <u>accessed September 2011</u>
- 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. 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.
- 7. The American College of Obstetricians and Gynecologists. ACOG Committee Opinion: number 280, December 2002. The role of the generalist obstetrician-gynecologist in the early detection of ovarian cancer. Obstet Gynecol 2002 Dec; 100(6):1413-6.
- Society of Gynecologic Oncologists Statement Regarding OvaSure[™] available at <u>http://www.sgo.org/WorkArea/showcontent.aspx?id=1846</u>. FDA letter to the manufacturer, August 7, 2008

Endnotes

¹ Based on expert opinion and MPRM 2.04.27A