EFFECTIVE DATE: 10|07|2014
POLICY LAST UPDATED: 09|19|2017

OVERVIEW
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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Measurements of CA 125 may be considered medically necessary in patients with symptoms suggestive of ovarian cancer or in those with known ovarian cancer or in individual patients with other gynecologic malignancies, such as endometrial cancer, in whom baseline levels of CA 125 have been shown to be elevated.

Measurement of CA 125 is considered not medically necessary in asymptomatic patients as a screening technique for ovarian cancer as the evidence is insufficient to determine the effects of the technology on health outcomes.

CA 125 is used for 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 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.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND
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.

CA 125 testing to monitor ovarian cancer and other gynecologic malignancies is considered standard practice. A large published randomized trial, conducted in the United States, found that screening asymptomatic women for ovarian cancer with CA 125 does not reduce ovarian cancer mortality but does result in unnecessary invasive procedures among women with false-positive test results.

A CA 125 level may be obtained as part of the initial pre-operative workup 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 CA 125 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.

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.

CODING

BlueCHiP for Medicare and Commercial Products

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

86304

ICD_10_CA_125_86304.pdf

RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations Policy
Multimarker Serum Testing Related to Ovarian Cancer
Serum Biomarker Human Epididymis Protein 4

PUBLISHED

Provider Update, November 2017
Provider Update, February, 2017
Provider Update, May 2016
Provider Update, July 2013
Provider Update, February 2012
Provider Update, April 2011
Provider Update, October 2009

REFERENCES

1. 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. Centers for Medicare and Medicaid Services cms.gov 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=AgAAgAAAAAAAAA%3d%3d&

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