

National Coverage Determination
Procedure Code: 86304
Tumor Antigen by Immunoassay CA 125
CMS Policy Number: 190.28
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Description: Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of these markers may reflect tumor size and grade.

This policy specifically addresses tumor antigen CA 125.

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 CA 125 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 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.

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.

Other:

Documentation Requirements: Indicated if service request for CA125 is requested more frequently than stipulated.

To review all requirements of this policy, please see: [CMS NCD listing by Chapter](#)

Covered ICD-10 Codes.

ICD-10	Descriptor
C45.1	Mesothelioma of peritoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malig neoplasm of ovrlp sites of retroperiton and peritoneum
C51.8	Malignant neoplasm of overlapping sites of vulva
C53.0	Malignant neoplasm of endocervix
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
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of ovrlp sites of female genital organs
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
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
D39.2	Neoplasm of uncertain behavior of placenta
D39.8	Neoplasm of uncertain behavior of oth female genital organs
D39.9	Neoplasm of uncertain behavior of female genital organ, unsp
G89.3	Neoplasm related pain (acute) (chronic)
M33.03	Juvenile dermatomyositis without myopathy
M33.13	Other dermatomyositis without myopathy
M33.93	Dermatopolymyositis, unspecified without myopathy
R19.09	Other intra-abdominal and pelvic swelling, mass and lump
R97.1	Elevated cancer antigen 125 [CA 125]
R97.8	Other abnormal tumor markers
Z85.41	Personal history of malignant neoplasm of cervix uteri
Z85.42	Personal history of malignant neoplasm of oth prt uterus
Z85.43	Personal history of malignant neoplasm of ovary
Z85.44	Personal history of malig neoplasm of female genital organs