Tumor Antigen by Immunoassay CA 125 (86304) - NCD 190.28

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.

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.

| Most Common Diagnoses (which meet medical necessity) * | |
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| C48.2 | Malignant neoplasm of peritoneum |
| C51.8 | Malignant neoplasm of overlapping sites of vulva |
| C53.0 | Malignant neoplasm of endocervix |
| C54.1 | Malignant neoplasm of endometrium |
| C54.9 | Malignant neoplasm of corpus uteri |
| C56.9 | Malignant neoplasm of ovary |
| C57.00 | Malignant neoplasm of fallopian tube |
| C79.60 | Secondary malignant neoplasm of ovary |
| C79.82 | Secondary malignant neoplasm of genital organs |
| D39.10 | Neoplasm of uncertain behavior of unspecified ovary |
| G89.3 | Neoplasm related pain |
| 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 |
| R19.09 | Other Intra-abdominal and pelvic swelling, mass and lump |
| R97.1 | Elevated cancer antigen 125 [CA 125] |

| R97.8 | Other abnormal tumor markers |
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| Z85.41 | Personal history of malignant neoplasm of cervix uteri |
| Z85.42 | Personal history of malignant neoplasm of other parts of uterus |
| Z85.43 | Personal history of malignant neoplasm of ovary |
| Z85.44 | Personal history of malignant neoplasm of other female genital organs |

^{*}For the full list of diagnoses that meet medical necessity see the Tumor Antigen by Immunoassay CA 125 National Coverage Determination 190.28 document.

The above CMS and WPS-GHA guidelines are current as of: 04/01/2025.