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

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Tracking Information

Publication Number

100-3

Manual Section Number

190.28

Manual Section Title

Tumor Antigen by Immunoassay - CA 125

Version Number

2

Effective Date of this Version

01/01/2006

Implementation Date

01/03/2006

Description Information

Benefit Category

Diagnostic Laboratory Tests

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service 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 and Limitations of Coverage

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.

(This NCD last reviewed November 2005)

Note: Scroll down for links to the quarterly Covered Code Lists (including narrative).

Cross Reference

Also see the <u>Medicare Claims Processing Manual</u>, Chapter 120, Clinical Laboratory Services Based on Negotiated Rulemaking.

Transmittal Information

Transmittal Number

47

Coverage Transmittal Link

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R47NCD.pdf

Revision History

07/2002 - Implemented NCD. Effective date 11/25/02. Implementation date 1/01/03. (TN AB-02-110) (CR 2130)

07/2004 - Published NCD in the NCD Manual without change to narrative contained in PM AB-02-110. Coding guidance now published in Medicare Lab NCD Manual. Effective and Implementation dates NA. (TN 17) (CR 2130)

02/2006 - Changes to the Covered Indications for Tumor Antigen by Immunoassay CA 125 to Add Primary Peritoneal Carcinoma. Effective Date: 01/01/2006. Implementation Date: 01/03/2006. (TN 47) (CR 4257)

Other

Covered Code Lists (including narrative)

July 2022 (PDF) (<u>ICD-10</u>) April 2022 (PDF) (ICD-10) January 2022 (PDF) (<u>ICD-10</u>) October 2021 (PDF) (<u>ICD-10</u>) July 2021 (PDF) (ICD-10) April 2021 (PDF) (ICD-10) January 2021 (PDF) (<u>ICD-10</u>) October 2020 (PDF) (ICD-10) July 2020 (PDF) (ICD-10) April 2020 (PDF) (ICD-10) January 2020 (PDF) (<u>ICD-10</u>) October 2019 (PDF) (ICD-10) July 2019 (PDF) (<u>ICD-10</u>) April 2019 (PDF) (ICD-10) January 2019 (PDF) (ICD-10) October 2018 (PDF) (<u>ICD-10</u>) July 2018 (PDF) (ICD-10) April 2018 (PDF) (ICD-10) January 2018 (<u>ICD-10</u>) October 2017 (ICD-10) July 2017 (<u>ICD-10</u>) April 2017 (ICD-10) January 2017 (<u>ICD-10</u>) October 2016 (ICD-10) January 2016 (<u>ICD-10</u>) October 2015 (<u>ICD-10</u>, <u>ICD-9</u>) October 2014 (<u>ICD-10</u>, <u>ICD-9</u>)

Changes to Lab NCD Edit Software

January 2022
October 2021
July 2021
October 2020
April 2020
January 2020
October 2019
July 2019
January 2019
October 2018
April 2018
January 2018
July 2017

April 2017 January 2017 January 2016

April 2022

National Coverage Analyses (NCAs)

This NCD has been or is currently being reviewed under the National Coverage Determination process. The following are existing associations with NCAs, from the National Coverage Analyses database.

• First reconsideration for Tumor Antigen by Immunoassay CA 125 (Addition of Primary Peritoneal Adenocarcinoma as a Covered Indication) (CAG-00290R)

Coding Analyses for Labs (CALs)

This NCD has been or is currently being reviewed under the National Coverage Determination process. The following are existing associations with CALs, from the Coding Analyses for Labs database.

- Original Consideration for Tumor Antigen Immunoassay CA 125 (Revision to Include Additional Personal History of Malignancy Codes) (CAG-00245N)
- Original Consideration for Tumor Antigen by Immunoassay CA 19-9 (Modification of Code List to Include ICD-9-CM Code 156.2, Malignant neoplasm of Ampulla of Vater) (CAG-00275N)
- Original Consideration for Tumor Antigen by Immunoassay CA 125 (Modification of Code List to Include ICD-9-CM Codes for Suspicious Ovarian Mass) (CAG-00284N)

Additional Information

Other Versions

Title	Version	Effective Between
Tumor Antigen by Immunoassay - CA 125	2	01/01/2006 - N/A
Tumor Antigen by Immunoassay - CA 125	1	11/25/2002 - 01/01/2006