Decision Memo for Tumor Antigen by Immunoassay CA 125 (Modification of Code List to Include ICD-9-CM Codes for Suspicious Ovarian Mass) (CAG-00284N)

Decision Summary

CMS has determined that ICD-9-CM diagnosis code 789.39, Abdominal or pelvic swelling, mass or lump of other specified site, flows from the existing narrative for conditions for which tumor antigen by immunoassay CA 125 is reasonable and necessary. We intend to modify the list of “ICD-9-CM Codes Covered by Medicare” in the NCD for tumor antigen by immunoassay CA 125 to include this code.

CMS has determined that ICD-9-CM codes related to suspicious mass to the NCD for Carcinoembryonic Antigen do not flow from the narrative and we will not make any changes to the list.

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Decision Memo

This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of ICD-9-CM Codes Covered that are linked to one of the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-4, Chapter 16, section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.

To: Administrative File: CAG-00284N Tumor Antigen by Immunoassay CA 125 (Modification of Code List to Include ICD-9-CM Codes for Suspicious Ovarian Mass)

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Re: Coding Analyses for Tumor Antigen by Immunoassay CA 125

Date: March 15, 2005

I. Decision

CMS has determined that ICD-9-CM diagnosis code 789.39, Abdominal or pelvic swelling, mass or lump of other specified site, flows from the existing narrative for conditions for which tumor antigen by immunoassay CA 125 is reasonable and necessary. We intend to modify the list of "ICD-9-CM Codes Covered by Medicare" in the NCD for tumor antigen by immunoassay CA 125 to include this code.

CMS has determined that ICD-9-CM codes related to suspicious mass to the NCD for Carcinoembryonic Antigen do not flow from the narrative and we will not make any changes to the list.

II. Background

On January 28, 2005, CMS began a coding analysis for expansion of the ICD-9-CM covered codes list for the tumor antigen by immunoassay CA 125 NCD. 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. CA 125 is a high molecular weight serum tumor marker elevated in 80 percent 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.

III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. These NCDs included the tumor antigen by immunoassay CA 125. The rule was proposed in the March 10, 2000 edition of the *Federal Register* (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled “ICD-9-CM Codes Covered by Medicare,” and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled “ICD-9-CM Codes Denied,” and lists diagnosis codes that are never covered by Medicare. The third list is entitled “ICD-9-CM Codes that do not Support Medical Necessity,” and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in the tumor antigen by immunoassay CA 125 NCD that any ICD-9-CM code not listed in either of the ICD-9-CM covered or denied sections would be categorized into this group that does not support medical necessity.

IV. Timeline of Recent Activities

On January 28, 2005, CMS open a coding analysis item regarding tumor antigen by immunoassay CA 125 after receiving a request from Jan Elston, MD of Surgical Associates of Zanesville, Incorporated located in Ohio. Dr. Elston’s request was for the addition of ICD-9-CM codes 793.6, Nonspecific abnormal finding on radiological and other examination of abdominal area, including retroperitoneum, and ICD-9-CM code 239.5, Neoplasms of unspecified nature in other genitourinary organs, to the list of ICD-9-CM Codes Covered by Medicare for both the tumor antigen by immunoassay CA 125 and Carcinoembryonic Antigen (CEA) NCDs.

We posted a tracking sheet to the Internet site (http://cms.hhs.gov/mcd/viewtrackingsheet.asp?id=149), soliciting public comment for 30 days on the appropriateness of adding codes 793.6, 239.5 and 789.39 to the list of covered diagnoses for tumor antigen by immunoassay CA 125 and CEA. At the end of the public comment period, February 26, 2005, we had received three comments. All three of the comments expressed support for the proposed addition of all three ICD-9-CM codes for both NCDs. The comments did not provide any scientific literature or substantive rationale to support their conclusions.

V. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

VI. CMS Analysis

As noted above, we have taken the position that the "ICD-9-CM Codes Covered by Medicare" list is intended to contain only those codes that flow from the narrative of the indication in the NCD. The tumor antigen immunoassay CA 125 NCD lists the following as an indication for testing:

"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."

Clearly this statement supports the inclusion of the appropriate ICD-9-CM code or codes for suspicious pelvic mass in the list of ICD-9-CM Codes Covered by Medicare. The requester suggested ICD-9-CM codes 793.6, Nonspecific abnormal finding of radiological and other examination of abdominal area, including retroperitoneum, and 239.5, Neoplasms of unspecified nature in other genitourinary organs. However, since the pelvic mass has not been classified as a neoplasm, we do not believe it is appropriate to use ICD-9-CM code 239.5 to indicate a suspicious mass. In fact, there is a note under category 239 that instructs coders not to use these codes for a mass. Further, we believe that code 793.6 is too non-specific to be added to the list of covered codes for CA 125. This code can be used for a broad spectrum of non-specific indications and would result in inappropriate coverage. Instead, we believe ICD-9-CM code 789.39, Abdominal or pelvis swelling, mass, or lump or other specified site, is the most appropriate ICD-9-CM code to indicate the covered indication of suspicious pelvic mass.

We reviewed carefully the narrative indications for CEA. CEA is primarily useful in monitoring patient with colorectal carcinoma at decision-making points. It may be useful in monitoring some carcinomas where a more specific marker is not expressed by the tumor. There is no indication in the CEA narrative that the marker is useful in patients who do not have carcinoma. Unlike the CA-125 NCD, there is no mention of patients who merely present with suspicious masses. In posting the tracking sheet for this request, we noted that the request was made without identifying a provision in the covered indications to support coverage, and no commenter during the public comment period provided a provision they believed would support coverage. Therefore, we do not believe any of the suggested codes flow from the narrative of CEA and we are not making changes to the list of ICD-9-CM Codes Covered by Medicare for CEA at this time.

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