CMS Manual System

Pub 100-03 Medicare National Coverage Determinations

Transmittal 47

Department of Health & Human Services (DHHS)

Center for Medicare & Medicaid Services (CMS)

Date: FEBRUARY 24, 2006

Change Request 4257

SUBJECT: Changes to the Covered Indications for Tumor Antigen by Immunoassay CA 125 to Add Primary Peritoneal Carcinoma

I. SUMMARY OF CHANGES: This transmittal modifies the national coverage determination (NCD) for Tumor Antigen by Immunoassay CA 125 to add primary peritoneal carcinoma as a covered indication for the test in accordance with the decision memorandum issued in CAG-00290R on the coverage Web site at cms.hhs.gov/coverage. System changes to implement this policy change were included in the January update to the laboratory NCD edit module software in accordance with CR 4161, transmittal 758 dated November 18, 2005. This transmittal serves only to manualize the change.

System changes for this manual provision were already included in CR 4161 which was released with a January 1, 2006 effective date.

System changes for this manual provision were already included in CR 4161 which was released with a January 3, 2006 target implementation date.

NEW/REVISED MATERIAL:
EFFECTIVE DATE: January 1, 2006
IMPLEMENTATION DATES: January 3, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/190.28/ Tumor Antigen by Immunoassay - CA 125

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-03	Transmittal: 47	Date: February 24, 2006	Change Request 4257

SUBJECT: Changes to the Covered Indications for Tumor Antigen by Immunoassay CA 125 to Add Primary Peritoneal Carcinoma

I. GENERAL INFORMATION

A. Background: The national coverage determinations (NCDs) for clinical diagnostic laboratory services were developed by the laboratory negotiated rulemaking committee and published as a final rule on November 23, 2001. The Laboratory NCDs are detailed in Pub.100-03, the NCD Manual. Further, to ensure nationally uniform implementation of the policies, lists of covered codes are maintained through software that is updated quarterly under contract with Computer Sciences Corporation.

B. Policy: In accordance with the NCD process that is included under section 731 of the Medicare Modernization Act of 2003, we have reconsidered the covered indications for the NCD for Tumor Antigen by Immunoassay CA 125 and have determined that the test is reasonable and necessary for surveillance of primary peritoneal carcinoma in Medicare beneficiaries following treatment. A decision memorandum explaining this change can be found on the Internet at http://www.cms.hhs.gov/coverage/default.asp by clicking national coverage analysis. This change becomes effective for services furnished on or after January 1, 2006. The systems changes implementing this were included in CR 4161, transmittal 758 dated November 18, 2005, announcing the January updates to the laboratory edit module.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
4257.1	Contractors shall implement changes as outlined in CR 4161, issued 11/18/2005. This CR manualizes those changes.	X		X						

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)

		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	None.									

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: January 1, 2006 **Implementation Date:** January 3, 2006 **Pre-Implementation Contact(s):** Jackie Sheridan-Moore 410-786-4635, jacqueline.sheridan@cms.hhs.gov **Post-Implementation Contact(s):** ROs	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

***Unless otherwise specified, the effective date is the date of service.**

190.28 - Tumor Antigen by Immunoassay – CA 125

(Rev.47, Issued: 02-24-06, Effective: 01-01-06, Implementation: 01-03-06)

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

The 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 *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.

(This NCD last reviewed November 2005)