

MARYLAND MEDICARE PART A**Policy No:** 97-07-R4**Topic:** **Immunoassay for Tumor Antigen**

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Beginning Effective Date

April 28, 1997

Ending Effective Date

11/24/2002

Description

Radioimmunoassay and immunohistochemical 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.

Policy Type

Local Medical Review Policy

Indications and Limitations of Coverage and/or Medical Necessity:

The following tests are not covered. They are not considered medically necessary for the diagnosis and treatment of diseases:

a2-PAG Pregnancy-Associated-Alpha2 Glycoprotein

BCM Breast Cancer Mucin

CA 19-9 Cancer Antigen 19-9

CA50 Cancer Antigen 50

CA72-4 Cancer Antigen 72-4

CA195 Cancer Antigen 195

CA242	Cancer Antigen 242
CA549	Cancer Antigen 549
CA-SCC	Squamous Cell Carcinoma
CAM17-1	Monoclonal Antimucin Antibody 17-1
CAM26	Monoclonal Antimucin Antibody 26
CAM29	Monoclonal Antimucin Antibody 29
CAR3	Antigenic determinant recognized by monoclonal antibody AR3
DU-PAN-2	Sialylated Carbohydrate Antigen DU-PAN-2
MCA	Mucin-like Carcinoma Associated Antigen
NSE	Neuron-Specific Enolase
P-LAP	Placental Alkaline Phosphatase
PNA-ELLA	Peanut Lectin Bonding Assay
SLEX	Sialylated Lewis X-Antigen
SLX	Sialylated SSEA-1 Antigen
SPAN-1	Sialylated Carbonated Antigen SPAN-1
ST-439	Sialylated Carbonated Antigen ST-439
TAG12	Tumor Associated Glycoprotein 12
TAG72	Tumor Associated Glycoprotein 72
TAG72.3	Tumor Associated Glycoprotein 72.3
TATI	Tumor Associated Trypsin Inhibitor
TNF-A	Tumor Necrosis Factor Alpha
TPA	Tissue Polypeptide Antigen

HCPCS Section/Benefit Category

Pathology and Laboratory/Chemistry/Immunology

Type of Bill

Not included in the development of this policy.

Revenue Code

Not included in the development of this policy.

HCPCS Codes

82105 *Alpha-fetoprotein; serum*

82378 *Carcinoembryonic antigen (CEA)*

84702 *Gonadotropin, chorionic (hCG); quantitative*

84703 *qualitative*

86294 *Immunoassay for tumor antigen, qualitative or semiquantitative (e.g., bladder tumor antigen)*

86300 *Immunoassay for tumor antigen, quantitative; CA 15-3(27.29)*

86301 *CA 19-9*

86304 *CA 125*

86316 *Immunoassay for tumor antigen (e.g., cancer antigen 125), each (for services **before January 1, 2001**)*

*other antigen, quantitative (e.g., CA 50, 72-4, 549), each (for services **as of January 1, 2001**)*

86849 *Unlisted immunology procedure*

ICD-9-CM Codes that Support Medical Necessity

Code 82105

Covered for:

070.22-070.23 *Viral hepatitis B with hepatic coma*

070.32-070.33 *Viral hepatitis B without mention of hepatic coma*

070.44 *Chronic hepatitis C with hepatic coma*

070.54 *Chronic hepatitis C without mention of hepatic coma*

155.0-155.2 *Malignant neoplasm of the liver and intrahepatic bile ducts*

174.0 *Malignant neoplasm of female breast, nipple, and areola*

174.1 *central portion*

174.2 *upper-inner quadrant*

174.3 *lower-inner quadrant*

174.4 *upper-outer quadrant*

174.5 *lower-outer quadrant*

174.6 *axillary tail*

174.8 *other specified sites*

174.9 *unspecified*

175.0	Malignant neoplasm of male breast
175.9	Other and unspecified sites of male breast
183.0	Malignant neoplasm of the ovary
186.0	Malignant neoplasm of undescended testis
186.9	Malignant neoplasm, other and unspecified testis
188.0	Malignant neoplasm of bladder; trigone of urinary bladder
188.1	dome of urinary bladder
188.2	lateral wall of urinary bladder
188.3	anterior wall of urinary bladder
188.4	posterior wall of urinary bladder
188.5	bladder neck
188.6	ureteric orifice
188.7	urachus
188.8	other specified sites of bladder
188.9	urinary organ, site unspecified
197.7	Secondary malignant neoplasm of liver, specified as secondary
198.1	Secondary malignant neoplasm of other specified sites, other urinary organs
198.6	Secondary malignant neoplasm of ovary
198.81	Secondary malignant neoplasm of other specified sites, breast
198.82	Secondary malignant neoplasm, genital organs
230.8	Carcinoma in situ of liver and biliary system
233.3	Carcinoma in situ of other and unspecified female genital organs
233.6	Carcinoma in situ of other and unspecified male genital organs
233.7	Carcinoma in situ of breast and genitourinary system, bladder
239.4	Neoplasms of unspecified nature, bladder
571.40	Chronic hepatitis, unspecified
571.41	Chronic persistent hepatitis
571.49	Other, chronic hepatitis
751.61	Biliary atresia

- 774.4 Perinatal jaundice due to hepatocellular damage
- 789.1 Hepatomegaly
- V10.3 Personal history of malignant neoplasm, breast
- V10.43 Personal history of malignant neoplasm, ovary
- V10.47 Personal history of malignant neoplasm, testis
- V10.51 Personal history of malignant neoplasm, urinary organs,
bladder
- V67.2 Follow-up examination following chemotherapy

Code 82378**Covered for:**

- 152.0-152.3 Malignant neoplasm of small intestine, including duodenum
- 152.8-152.9
- 153.0-153.9 Malignant neoplasm of the colon
- 154.0-154.3 Malignant neoplasm of rectum rectosigmoid junction, and anus
- 154.8
- 159.0 Malignant neoplasm of other ill-defined sites within the intestinal
tract
- 162.0 Malignant neoplasm of trachea
- 162.2 Malignant neoplasm of main bronchus
- 162.3 Malignant neoplasm of upper lobe, bronchus or lung
- 162.4 Malignant neoplasm of middle lobe, bronchus or lung
- 162.5 Malignant neoplasm of lower lobe, bronchus or lung
- 162.8 Malignant neoplasm of other parts of bronchus or lung
- 162.9 Malignant neoplasm of bronchus and lung, unspecified
- 175.0 Malignant neoplasm of female breast, nipple, and areola
 - 174.1 central portion
 - 174.2 upper-inner quadrant
 - 174.3 lower-inner quadrant
 - 174.4 upper-outer quadrant
 - 174.5 lower-outer quadrant

174.6	axillary tail
174.8	other specified sites
174.9	unspecified
175.0	Malignant neoplasm of male breast
175.9	
197.4	Secondary malignant neoplasm of small intestine
197.5	Secondary malignant neoplasm of large intestine
230.3	Carcinoma in situ of colon
230.4	Carcinoma in situ of rectum
230.7	Carcinoma in situ of other and unspecified part of intestine
235.2	Neoplasm of uncertain behavior of stomach, intestines, and rectum
V10.03	Personal history of malignant neoplasm, esophagus
V10.05	Personal history of malignant neoplasm, large intestine
V10.06	Personal history of malignant neoplasm, rectum, rectosigmoid junction, and anus

Codes 84702 and 84703

Covered for:

181	Malignant neoplasm of placenta
183.0	Malignant neoplasm, ovary
186.0	Malignant neoplasm of undescended testis
186.9	Malignant neoplasm other and unspecified testis
236.1	Neoplasm of uncertain behavior, placenta
630	Hydatidiform mole
V23.1	Pregnancy with history of trophoblastic disease
V71.1	Observation for suspected malignant neoplasm

Code 86294 –Use this procedure code for bladder tumor antigen **for dates of service on or after January 1, 2001.**

Before January 1, 2001, use procedure code 86316.

Covered for:

188.0	Malignant neoplasm of bladder; trigone of urinary bladder
188.1	dome of urinary bladder

188.2	lateral wall of urinary bladder
188.3	anterior wall of urinary bladder
188.4	posterior wall of urinary bladder
188.5	bladder neck
188.6	ureteric orifice
188.7	urachus
188.8	other specified sites of bladder
188.9	urinary organ, site unspecified
198.1	Secondary malignant neoplasm of other urinary organs
233.7	Carcinoma in situ of the bladder
239.4	Neoplasm of unspecified nature of the bladder
V10.51	Personal history of malignant neoplasm of the bladder
V67.2	Follow-up examination following chemotherapy

Code 86300**Covered for:**

174.0-	Malignant neoplasm of female breast; nipple, and areola
174.1	central portion
174.2	upper-inner quadrant
174.3	lower-inner quadrant
174.4	upper-outer quadrant
174.5	lower-outer quadrant
174.6	axillary tail
174.8	other specified sites
174.9	unspecified
175.0	Malignant neoplasm of male breast
175.9	Other and unspecified sites of male breast
198.81	Secondary malignant neoplasm of other specified sites breast
V67.2	Follow-up examination following chemotherapy

Code 86301 (CA 19-9)

This code is non-covered as it is considered to be experimental.

Code 86304 (CA 125)

183.0	Malignant neoplasm; ovary
183.2	fallopian tube
183.3	broad ligament
183.4	parametrium
183.5	round ligament
183.8	other specified sites of uterine adnexa
183.9	uterine adnexa, unspecified
V10.43	History of condition, ovary
V67.2	Follow-up examination following chemotherapy

Code 86316 (CA 125, CA 15-3, or CA 27-29)

The description of procedure code 86316 will change drastically as of January 1, 2001. For dates of service **before January 1, 2001**, the following limited coverage will apply:

Covered for:

174.0-174.6	Malignant neoplasm of female breast
174.8-174.9	
175.0	Malignant neoplasm of male breast
175.9	
183.0	Malignant neoplasm of the ovary
183.2-183.5	
183.8-183.9	Malignant neoplasm of other uterine adnexa
188.0-188.9	Malignant neoplasm of bladder
198.1	Secondary malignant neoplasm of other urinary organs
198.6	Secondary malignant neoplasm of ovary
233.3	Carcinoma in situ of unspecified female genital organs
233.7	Carcinoma in situ of the bladder
239.4	Neoplasm of unspecified nature of bladder
V10.43	History of condition, ovary
V10.51	Personal history of malignant neoplasm of the bladder
V67.2	Follow-up examination following chemotherapy

After January 1, 2001, the description for code 86316 will change as follows and will become non-covered:

86316 Immunoassay for tumor antigen; other antigen, quantitative (e.g., CA 50, 72-4, 549), each

Non-covered ICD-9-CM Code(s)

All diagnoses not listed in the “ICD-9-CM Codes that Support Medical Necessity” section of this policy.

HCFA National Policy

- Establishment of national policy supercedes all previous contractor policy statements, including Local Medical Policy coverage guidelines.
- Title XVIII of the Social Security Act, section 1862 (a) (7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, section 1862 (a) (1) (A). this section allows coverage and payment for only those services that are considered to be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Reasons for Denial

- All other indications not listed in the “Indications and Limitations of Coverage” section of this policy,
- HCPC code 86301, Immunoassay for Tumor Antigen, quantitative: CA 19-9 is considered to be experimental and therefore is non-covered by the Medicare Program,
- For services on or after January 1, 2001, HCPC code 86316 will be non-covered as experimental,
- The service is for screening purposes,
- The service is not medically necessary,
- The medical record does not verify that the service described by the HCPCS code was provided,
- The service does not follow the guidelines of this policy, and;

- (CA125) for making differential diagnosis of pelvic masses. Note: The sensitivity and specificity of the cancer antigen 125 test is unreliable for making differential diagnoses of pelvic masses.

Coding Guidelines

- To report these services, use the appropriate HCPCS code(S),
- All of the coverage criteria must be met before these services can be reimbursed by Medicare,
- Diagnosis(es) must be present on any claim submitted, and must be coded to the highest level of specificity,
- The diagnosis code(s) must be representative of the patient's condition,
- Claims submitted with code 86316, must contain the specific antigen for which testing is being performed, and;
- V8.9 (special screening tests for other conditions, unspecified condition should be used in the absence of any signs or symptoms, to indicate screening.

Documentation Requirements

Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available to Medicare upon request.

Other Comments

Medicare will continue to monitor the utilization of these laboratory tests through the Focused Medical Review (FMR) process.

Start Date of Comment Period

Start Date of Notice Period

March 28, 1997

Revision Date

- 07/28/99-Limited coverage expanded to maintain consistency in policies between carrier and intermediary. See 07/28/99 Provider Bulletin for specific changes.
- 11/17/2000-HCPCS code 86849 deleted, ICD-9-CM codes covered under HCPCS 86316. Coverage was expanded for HCPCS codes 82378 and 86316.
- 01/05/2001-Addition of new codes and changes in description of 86316. Refer to 01/05/2001 Provider Bulletin for further clarification of the changes.
- 04/09/2001-Addition of previously omitted code, 86294, which altered the limited coverage on codes 86300, 86301, and 86304. Refer to 04/09/2001 Provider Bulletin for clarification of changes.

Revision Number

- 97-07R1 (07/28/99)
- 97-07R2 (11/17/2000)
- 97-07R3 (01/05/2001)
- 97-07R4 (04/09/2001)

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