

If a conflict arises between a Clinical Payment and Coding Policy (“CPCP”) and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. “Plan documents” include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. BCBSIL may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSIL has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act (“HIPAA”) approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing (“UB”) Editor, American Medical Association (“AMA”), Current Procedural Terminology (“CPT®”), CPT® Assistant, Healthcare Common Procedure Coding System (“HCPCS”), ICD-10 CM and PCS, National Drug Codes (“NDC”), Diagnosis Related Group (“DRG”) guidelines, Centers for Medicare and Medicaid Services (“CMS”) National Correct Coding Initiative (“NCCI”) Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

## **Serum Tumor Markers for Malignancies**

**Policy Number: CPCPLAB037**

**Version 1.0**

**Enterprise Medical Policy Committee Approval Date: January 25, 2022**

**Plan Effective Date: May 1, 2022**

### **Description**

BCBSXX has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

### **Reimbursement Information:**

The use of the following serum tumor markers **may be reimbursable** for the following indications:

1. Alpha fetoprotein (AFP) testing for:
  - a. Suspected germ cell tumor metastasis from an unknown primary site:
    - i. Testicular mass
    - ii. Pelvic mass
    - iii. Mediastinal mass
    - iv. Peritoneal mass

- v. Retroperitoneal mass
  - vi. Intracranial mass
  - vii. Sacrococcygeal mass
- b. For diagnosis, staging, surveillance, and/or monitoring therapy in the following:
- i. Hepatocellular carcinoma
  - ii. Thymoma
  - iii. Thyroid carcinoma
  - iv. Testicular germ cell tumor/carcinoma
  - v. Ovarian germ cell tumor/carcinoma
  - vi. Sacrococcygeal teratoma
2. Alkaline Phosphatase (ALP) for
- a. Bone Cancers
3. Beta human chorionic gonadotropin (beta-HCG) for:
- a. Suspected germ cell tumor metastasis from an unknown primary site:
    - i. Testicular mass
    - ii. Pelvic mass
    - iii. Mediastinal mass
    - iv. Peritoneal mass
    - v. Retroperitoneal mass
    - vi. Intracranial mass
    - vii. Sacrococcygeal mass
  - b. For diagnosis, staging, surveillance, and/or monitoring therapy in the following:
    - i. Thymoma
    - ii. Thyroid carcinoma
    - iii. Testicular germ cell tumor/carcinoma
    - iv. Ovarian germ cell tumor/carcinoma
    - v. Sacrococcygeal teratoma
4. Beta-2 microglobulin (B2M) for:
- a. Multiple Myeloma initial diagnostic workup and follow-up/surveillance
  - b. Non-Hodgkin's Lymphoma workup
  - c. Waldenström's Macroglobulinemia/ Lymphoplasmacytic Lymphoma workup
  - d. Castleman's Disease workup
  - e. Follicular Lymphoma
  - f. Mantle Cell Lymphoma
  - g. Diffuse B-cell Lymphoma
  - h. AIDS-related B-cell Lymphoma
  - i. Lymphoblastic Lymphoma
  - j. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
  - k. Systemic Light Chain Amyloidosis initial diagnostic workup
5. Cancer Antigen 15-3 and 27.29 (CA 15-3 and 27-29) for:
- a. Metastatic breast cancer monitoring during active therapy
6. Cancer Antigen 19-9 (CA 19-9) for:
- a. Pancreatic adenocarcinoma workup, post treatment and surveillance
  - b. Gallbladder cancer workup and surveillance
  - c. Hepatobiliary carcinoma workup and post biliary decompression
  - d. Intrahepatic and extrahepatic cholangiocarcinoma workup
  - e. Pancreatic or biliary tract primary workup
  - f. Small bowel adenocarcinoma workup

- g. Epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer workup and monitoring
- 7. Cancer Antigen 125 (CA-125) for:
  - a. Epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer workup and monitoring
  - b. BRCA mutation-positive individuals age 30 and older who have not elected risk-reducing salpingo-oophorectomy (RRSO)
  - c. Borderline epithelial tumors (low malignant potential) monitoring
  - d. Endometrial Cancer for workup and surveillance
  - e. Occult Primary - adenocarcinoma or carcinoma not otherwise specified workup
- 8. Carcinoembryonic Antigen (CEA) for:
  - a. Colorectal carcinoma workup and surveillance every 3-6 months for 2 years, then every 6 months for a total of 5 years
  - b. Hepatobiliary Cancers including:
    - i. Intrahepatic Cholangiocarcinoma workup
    - ii. Extrahepatic Cholangiocarcinoma workup
    - iii. Gallbladder Cancer workup and surveillance
  - c. Medullary thyroid carcinoma workup and surveillance
  - d. Mucinous carcinoma of the ovary workup
  - e. Small bowel adenocarcinoma workup
  - f. Rectal cancer workup
  - g. Epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer workup and monitoring
- 9. Chromogranin A (CgA) for:
  - a. Neuroendocrine tumors of:
    - i. gastrointestinal tract
    - ii. lung
    - iii. thymus (carcinoid tumors) evaluation
- 10. Calcitonin (CALCA) expression for:
  - a. Medullary thyroid carcinoma workup, surveillance and post-surgical evaluation
  - b. Adenocarcinoma or anaplastic/undifferentiated tumors of the head and neck workup
- 11. Inhibin (INHA) expression for:
  - a. Undiagnosed pelvic mass workup for clinical indication to assess for LCOC (Less Common Ovarian Cancers) and pregnancy
  - b. Granulosa cell tumors observation
- 12. Lactate dehydrogenase (LDH) for:
  - a. Acute Lymphoblastic Leukemia (ALL) workup and Pediatric Acute Lymphoblastic Leukemia (PED-ALL)
  - b. Acute Myeloid Leukemia (AML) workup
  - c. B-cell lymphoma workup (including Castleman's disease)
  - d. Chronic Lymphocytic Leukemia workup
  - e. Hairy Cell Leukemia workup
  - f. Hodgkin's lymphoma workup
  - g. Ovarian cancer workup
  - h. Primary cutaneous B-cell Lymphoma workup
  - i. Non-Hodgkin's Lymphoma workup
  - j. Testicular germ cell tumors staging, prognosis before chemotherapy and/or additional surgery, monitoring response to treatment and detecting recurrence
  - k. Osteosarcoma and Ewing Sarcoma workup
  - l. Multiple Myeloma workup, follow-up/surveillance and staging
  - m. Myelodysplastic syndromes (initial evaluation)
  - n. Myeloproliferative neoplasms (initial evaluation)

- o. Cutaneous melanoma
- p. Kidney cancer
- q. Small cell lung cancer
- r. Systemic Light Chain Amyloidosis workup
- s. Waldenström's Macroglobulinemia/ Lymphoplasmacytic Lymphoma workup

13. Troponin T

- a. Systemic Light Chain Amyloidosis diagnostic workup

14. Tryptase

- a. Systemic Mastocytosis

The use of urokinase plasminogen activator (uPA) and plasminogen activator inhibitor type 1 (PAI-1) as serum tumor markers **is not reimbursable**.

Any of the tumor markers listed above for any cancer indication not otherwise listed and all other applications of serum tumor markers **are not reimbursable**, including but not limited to:

- a. A2-PAG (pregnancy associated alpha2 glycoprotein)
- b. AFP-L3 (Lens culinaris agglutinin reactive AFP)
- c. BCM (breast cancer mucin)
- d. CA-50 (cancer antigen 50)
- e. CA 72-4 (cancer antigen 72-4)
- f. CA-242 (cancer antigen 242)
- g. CA-195 (cancer antigen 195)
- h. CA-549 (cancer antigen 549)
- i. CAM 17-1 (antimucin monoclonal antibody)
- j. CAM-26 (carcinoma associated mucin antigen)
- k. CAM-29 (carcinoma associated mucin antigen)
- l. CA-SCC (squamous cell carcinoma antigen)
- m. CAR-3 (antigenic determinant recognized by monoclonal antibody AR-3)
- n. Circulating extracellular domain of HER2 (human epidermal growth factor receptor 2)
- o. DCP (Des-Gamma-Carboxy Prothrombin)
- p. DMSA (pentavalent technetium-99mm dimercaptosuccinic acid)
- q. Du-PAN-2 (sialylated carbohydrate antigen)
- r. Human epididymis protein (HE4)
- s. Ki-67 antigen for esophageal or breast cancer
- t. MCA (mucinous carcinoma associated antigen)
- u. MSA (mammary serum antigen)
- v. NSE (neuron specific enolase)
- w. P-LAP (placental alkaline phosphatase)
- x. PNA-ELLA (peanut lectin bonding assay)
- y. P53 (monoclonal antibody)
- z. SLEX (sialylated Lewis-X antigen)
- aa. SLX (sialylated SSEA-1 antigen)
- bb. SPAN-1 (sialylated carbonated antigen SPAN-1)
- cc. ST-439 (sialylated carbohydrate antigen ST-439)
- dd. TAG-12 (tumor associated glycoprotein 12)
- ee. TAG 72 (tumor associated glycoprotein 72)
- ff. TAG-72-3 (tumor associated glycoprotein 72-3)
- gg. TNF-alpha (TNF-a) (tumor necrosis factor alpha)

- hh. TATI (tumor associated trypsin inhibitor)
- ii. TPA (tissue polypeptide antigen)
- jj. TPS (tissue polypeptide specific antigen)

The following tests **are not reimbursable** for all indications:

- a. Apifyn®
- b. BeScreened™ (BeScreened™ -CRC)
- c. Carcinoembryonic antigen cell adhesion molecule 6 (CEACAM6) for predicting the risk of breast cancer
- d. Carcinoembryonic antigen cellular adhesion molecule-7 (CEACAM-7) expression as a predictive marker for rectal cancer recurrence
- e. Cofilin (CFL1) as a prognostic and drug resistance marker in non-small cell lung cancer.
- f. ColonSentry test for screening of colorectal cancer.
- g. ColoPrint, CIMP, LINE-1 hypomethylation, and Immune cells for colon cancer.
- h. Colorectal Cancer DSA (Almac Diagnostics, Craigavon, UK)
- i. EarlyCDT-Lung test
- j. HE4 immunoassay
- k. HERmark®
- l. Mucin 4 expression as a predictor of survival in colorectal cancer.
- m. OVA1™
- n. Ova Check™
- o. OvaSure™
- p. Overa (OVA1 Next Generation)
- q. Panexia test
- r. PreOvar test for the KRAS-variant to determine ovarian cancer risk.
- s. REVEAL Lung Nodule Characterization
- t. ROMA™
- u. VeriStrat®
- v. Xpresys Lung Test

Analysis of proteomic patterns in serum for screening and detection of cancer **is not reimbursable**.

## Procedure Codes

Codes
81500, 81503, 81538, 81599, 82105, 82107, 82232, 82308, 82378, 82397, 83520, 83615, 83950, 83951, 84075, 84078, 84080, 84484, 84702, 84703, 84704, 84999, 85415, 86300, 86301, 86304, 86305, 86316, 86336, 0003U, 0067U, 0092U, 0163U

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### Policy Update History:

5/1/2022	New policy
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