**DRAFT Medical Coverage Policy |** Serum Tumor Markers for Breast and Gastrointestinal Malignancies

**EFFECTIVE DATE:** 01|01|2024
**POLICY LAST UPDATED:** 10|02|2023

## OVERVIEW
This policy addresses the coverage for tumor markers only when utilized for the management of cancerous conditions. Tumor markers are substances produced in low quantities by tumor cells or other cells of the body in response to the presence of cancer or certain benign conditions.

## MEDICAL CRITERIA
Not applicable

## PRIOR AUTHORIZATION
Not applicable

## POLICY STATEMENT
**Medicare Advantage Plans**
For the noted immunoassay tests for tumor antigens CA 15-3 (CA 27.29) or CA 19-9, refer to the Related Policies section for Medicare Advantage Plans National and Local Coverage Determinations.

Immunoassay test for tumor antigen, other antigen (e.g., CA 50, 72-4, 549) is considered not covered when filed with one of the diagnosis codes listed in the Coding section of this policy.

**Commercial Products**
The noted immunoassay tests for tumor antigens CA 15-3 (CA 27.29) or CA 19-9 are covered when filed with one of the covered diagnosis codes listed in the Coding section of this policy.

Immunoassay test for tumor antigen, other antigen (e.g., CA 50, 72-4, 549) is considered not medically necessary when filed with one of the diagnosis codes listed in the Coding section of this policy.

Some genetic testing services are not covered and a contract exclusion for any self-funded group that has excluded the expanded coverage of biomarker testing related to the state mandate, R.I.G.L. **§27-19-81** described in the Biomarker Testing Mandate policy. For these groups, a list of which genetic testing services are covered with prior authorization, are not medically necessary or are not covered because they are a contract exclusion can be found in the Coding section of the Genetic Testing Services or Proprietary Laboratory Analyses policies. Please refer to the appropriate Benefit Booklet to determine whether the member's plan has customized benefit coverage. Please refer to the list of Related Policies for more information.

## COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

## BACKGROUND
Serum tumor markers are molecules or substances shed by a tumor into the circulation where they can be detected and quantitated. Noncirculating tumor markers include those that can be detected histochemically or cytogenetically on a tissue sample. Examples of the latter include the HER2 oncoprotein, detected by

immunohistochemistry on a subset of breast cancers, and the Philadelphia chromosome, which is a cytogenetic marker for chronic myelogenous leukemia.

Serum tumor markers have been investigated in many malignancies, including most prominently myeloma (i.e., β2-microglobulin), germ cell tumors (i.e., alpha fetoprotein, human chorionic gonadotropin), and prostate cancer (i.e., PSA). The HER2 oncoprotein extracellular domain has been studied as a serum tumor marker in breast and other malignancies. Carcinoembryonic antigen (CEA) has also been widely investigated in gastrointestinal malignancies. This policy focuses on specific tumor markers for breast and gastrointestinal malignancies.

For breast cancer, the most extensively investigated serum tumor markers besides HER2 are those associated with the MUC-1 gene. For gastrointestinal cancer, including gastric, pancreatic, and colorectal cancer, the most extensively studied tumor markers, other than CEA, are those related to mucinous glycoproteins. The MUC-1 gene encodes a cell-associated mucin-like antigen, and different antibodies may be used to detect different epitopes. CA 15-3 and CA 27.29 are two related monoclonal antibodies that detect epitopes encoded by the MUC-1 gene. While much of the literature has focused on the use of CA 15-3, it has been largely replaced by CA 27.29, which is reportedly more sensitive. The mucinous glycoproteins of the gastrointestinal tract include CA 19-9, and CA 72-4, depending on which antibody is used.

Since serum tumor markers can also be detected in normal or benign lesions, significantly elevated circulating levels may occur with malignancy by one or more of the following mechanisms: (1) overexpression of the antigen by malignant cells; (2) a large tumor burden; and/or (3) slower clearance of the marker. For example, since most tumor markers are cleared by the liver, liver abnormalities (whether benign, malignant, or inflammatory) may elevate tumor marker concentrations due to impaired clearance. Because most tumor markers are not unique to malignancy, cut-off points must be established for normal versus abnormal marker levels. In contrast, serial monitoring of serum tumor markers in a setting of established malignancy may not require such cutoff points. Various clinical applications of serum tumor markers can be broadly divided into 2 categories, those involving a single measurement and those involving serial measurements.

Measurement of serum tumor marker CA 72-4 is considered not medically necessary as a technique to diagnose, determine prognosis, select therapy, assess response to therapy, or monitor for recurrence of either breast or gastrointestinal malignancies. Gastrointestinal malignancies include gastric, pancreatic, and colorectal cancer. Therefore, this test is not medically necessary for Commercial products.

## CODING

**Medicare Advantage Plans**

See related policy for Medicare Advantage Plans National and Local Coverage Determinations for the noted immunoassay tests for tumor antigens CA 15-3 (CA 27.29) or CA 19-9:

**86300** Immunoassay for tumor antigen, quantitative; CA 15-3 (CA 27.29)
**86301** Immunoassay for tumor antigen, quantitative; CA 19-9

The following CPT code(s) are not covered when filed with one of the ICD-10-CM codes, listed below. Note: This CPT code can be used for testing for more indications than are referenced in this policy. Please see the Related Policies section.

**86316** Immunoassay for tumor antigen, other antigen, quantitative (eg, CA 50, 72-4, 549), each

**ICD-10-CM**

C16.0-C16.9
C18.0-C18.9
C19
C20
C21.0-C21.8
C25.0-C25.9

C50.01-C50.929

**Commercial Products**
The following immunoassay tests are covered when filed with one of the diagnosis codes in the attachments below:
**86300** Immunoassay for tumor antigen, quantitative; CA 15-3 (CA 27.29)
**ICD-10 Codes 86300**
**86301** Immunoassay for tumor antigen, quantitative; CA 19-9
**ICD-10 Codes 86301**

The following CPT code(s) are not medically necessary when filed with one of the ICD-10-CM codes, listed below.
Note: This CPT code can be used for testing for more conditions/diagnoses than are referenced in this policy. Please see the Related Policies section for other not covered and not medically necessary conditions/diagnoses.
**86316** Immunoassay for tumor antigen, other antigen, quantitative (eg, CA 50, 72-4, 549), each

**ICD-10-CM**
C16.0-C16.9
C18.0-C18.9
C19
C20
C21.0-C21.8
C25.0-C25.9
C50.01-C50.929

## RELATED POLICIES
Biomarker Testing Mandate
Genetic Testing Services
Medicare Advantage Plans National and Local Coverage Determinations Policy
Genetic and Protein Biomarkers for the Diagnosis and Cancer Risk Assessment of Prostate Cancer
Urinary Biomarkers for Cancer Screening, Diagnosis and Surveillance

## PUBLISHED
Provider Update, November 2023
Provider Update, October 2022
Provider Update, April 2021
Provider Update, May 2020
Provider Update, June 2019

## REFERENCES

1. Centers for Medicare and Medicaid Services. NCD for Tumor Antigen by Immunoassay - CA 15-3/CA 27.29 (190.29). https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=134&ncdver=1&bc=0
2. Centers for Medicare and Medicaid Services. NCD for Tumor Antigen by IMMUNOASSAY - CA 19-9 (190.30). https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=142&ncdver=1&bc=0

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