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

EFFECTIVE DATE: 05|01|2026
POLICY LAST REVIEWED: 06|03|2026

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

Note: Laboratories are not allowed to obtain clinical authorization or participate in the authorization process on behalf of the ordering physician. Only the ordering physician shall be involved in the authorization, appeal or other administrative processes related to prior authorization/medical necessity.

In no circumstance shall a laboratory or a physician/provider use a representative of a laboratory or anyone with a relationship to a laboratory and/or a third party to obtain authorization on behalf of the ordering physician, to facilitate any portion of the authorization process or any subsequent appeal of a claim where the authorization process was not followed and/or a denial for clinical appropriateness was issued, including any element of the preparation of necessary documentation of clinical appropriateness. If a laboratory or a third party is found to be supporting any portion of the authorization process, BCBSRI will deem the action a violation of this policy and severe action will be taken up to and including termination from the BCBSRI provider network. If a laboratory provides a laboratory service that has not been authorized, the service will be denied as the financial liability of the participating laboratory and may not be billed to the member.

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.

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.

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 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.

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

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

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

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Provider Update, March/August 2026
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Provider Update, October 2024
Provider Update, November 2023
Provider Update, October 2022

REFERENCES

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4. 1996 TEC Assessments; Tab 23: Serum tumor markers for the diagnosis and monitoring of gastrointestinal cancer.
5. 1996 TEC Assessments; Tab 24: Serum tumor markers (CA 15-3, CA 27.29 and CA 549) for the monitoring of breast cancer recurrence.
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