Tumor Antigen Assays

MEDICAL POLICY NUMBER: 414

Effective Date: 6/1/2024

Last Review Date: 5/2024

Next Annual Review: 5/2025

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Tumor Antigen Assays: PHP members must meet the testing criteria governed by the Oregon Health Plan (OHP) Prioritized List of Health Services and the OHP Diagnostic Procedure Codes / Procedure Group 1119. Diagnostic services needed to establish a diagnosis are covered regardless of where the ultimate diagnosis appears on the Prioritized List. Once the diagnosis is determined, coverage of further treatment is reimbursed if the service appears in the funded region of the list for that condition.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

I. Testing for CA 125 may be considered **medically necessary** when any of the following are met (A.-C.):
   - A. 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**; or**
   - B. During the first month of post-treatment after initial surgery and/or chemotherapy for ovarian carcinoma; **or**
   - C. At the completion of chemotherapy.

II. Testing for CA 125 is considered **not medically necessary** when criterion I. above is not met, including but not limited to the following:
   - A. Evaluation of patients with signs or symptoms suggestive of malignancy;
   - B. Aiding in the differential diagnosis of patients with a pelvic mass.

III. Testing for CA 15-3 or CA 7.29 may be considered **medically necessary** to aid in the management of patients with breast cancer, including assessment of the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

IV. Testing for CA 15-3 or CA 7.29 is considered **not medically necessary** when criterion III. above is not met, including but not limited to evaluation of patients with signs or symptoms suggestive of malignancy.

V. Testing for CA 19-9 is considered **medically necessary** to aid in the management of patients with established diagnosis of pancreatic and biliary ductal carcinoma, including assessment of the presence of recurrent disease, or the patient's response to treatment with subsequent treatment cycles.

VI. Testing for CA 19-9 is considered **not medically necessary** when criterion V. above is not met, including but not limited to the following:

A. Evaluation of patients with signs or symptoms suggestive of malignancy;
B. Diagnosing pancreatic or biliary ductal carcinoma.

Link to Evidence Summary

POLICY CROSS REFERENCES

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

This policy may be primarily based on the following Center for Medicare and Medicaid Services (CMS) guidance resources:

- National Coverage Determination (NCD) for Tumor Antigen by Immunoassay – CA125 9 (NCD 190.28)[1]
- National Coverage Determination (NCD) for Tumor Antigen by Immunoassay – CA15-3/CA 27.29 (NCD 190.29)[2]
- National Coverage Determination (NCD) for Tumor Antigen by Immunoassay – CA 19-9 (NCD 190.30)[3]
- Medicare NCD Coding Policy Manual and Change Report (ICD-10-CM).[4]

BACKGROUND

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 the following tumor antigen: CA 125, CA 19-9, CA 15-3 and CA 27.29.

CA 125

CA 125 is a high molecular weight serum tumor marker elevated in 80% 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 CA125 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 CA125 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.

CA 15-3/CA 27.29

Multiple tumor markers are available for monitoring the response of certain malignancies to therapy and assessing whether residual tumor exists post-surgical therapy.

CA 15-3 is often medically necessary to aid in the management of patients with breast cancer. Serial testing must be used in conjunction with other clinical methods for monitoring breast cancer. For monitoring, if medically necessary, use consistently either CA 15-3 or CA 27.29, not both.

CA 27.29 is equivalent to CA 15-3 in its usage in management of patients with breast cancer.

CA 19-9

Multiple tumor markers are available for monitoring the response of certain malignancies to therapy and assessing whether residual tumor exists post-surgical therapy.

Levels are useful in following the course of patients with established diagnosis of pancreatic and biliary ductal carcinoma. The test is not indicated for diagnosing these two diseases.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

BILLING GUIDELINES AND CODING

The CPT/HCPCS codes below may be considered **medically necessary** when billed with one of the ICD-10 codes included in the most recent "Medicare National Coverage Determinations (NCD) Coding Policy

Manual and Change Report (ICD-10-CM)," available for download at "Lab NCDs – ICD-10." Please see the coding policy manual for a complete list of diagnosis codes.

CODES*		
CPT	86300	Immunoassay for tumor antigen, quantitative; CA 15-3 (27.29)
	86301	Immunoassay for tumor antigen, quantitative; CA 19-9
	86304	Immunoassay for tumor antigen, quantitative; CA 125
HCPCS	None	

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Tumor Antigen by Immunoassay – CA125 9 (NCD 190.28). https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=130. Published 2006. Accessed 4/4/2024.
2. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Tumor Antigen by Immunoassay - CA 15-3/CA 27.29 (NCD 190.29). https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=134. Published 2003. Accessed 4/4/2024.
3. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Tumor Antigen by Immunoassay - CA 19-9 (NCD 190.30). https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=142. Published 2003. Accessed 4/4/2024.
4. Centers for Medicare & Medicaid Services. Lab NCDs - ICD-10. https://www.cms.gov/medicare/coverage/determination-process/basics/lab-ncds-icd-10. Published 2024. Accessed 4/10/2024.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
6/2024	New policy.