

Medicare Medical Policy

Tumor Antigen Assays

MEDICARE MEDICAL POLICY NUMBER: XXX

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

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

PRODUCT AND BENEFIT APPLICATION

Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
<i>Tumor Antigen CA 125</i>	National Coverage Determination (NCD): Tumor Antigen by Immunoassay - CA 125 (190.28)
<i>Tumor Antigen CA 15-3 and CA 27.29</i>	NCD: Tumor Antigen by Immunoassay - CA 15-3/CA 27.29 (190.29)
<i>Tumor Antigen CA 19-9</i>	NCD: Tumor Antigen by Immunoassay - CA 19-9 (190.30)

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (*Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021*)

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

This policy is based on guidance published by the Centers for Medicare and Medicaid Services (CMS).

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment

policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

The following CPT/HCPCS codes may be covered when billed with one of the ICD-10 codes that Medicare has included as medically necessary 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](#). Select the “Lab Code List ICD10 (ZIP)” file option that aligns with the date services were or will be rendered from the Downloads section. Open a spreadsheet and look for NCDs 190.28, 190.29, and/or 190.30 in column A. This resource can also be accessed directly from the NCD noted above, under “Revision History” and by selecting the applicable “Covered Code List” version. While these services do not require prior authorization, utilization may be subject to audit and all criteria from NCD 190.28, 190.29, and/or 190.30, as appropriate to the test in question, must be met. Thus, inclusion of a diagnosis (ICD-10) code on this list may not warrant automatic coverage.

For additional billing guidance, including test coverage and utilization limitations (including repeat testing billing instructions), see the applicable NCD above.

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 code list above 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. According to Medicare, “presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare.” The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. (*Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician’s Fee Schedule, A. Physician’s Services*)
- 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. CMS Lab NCDs - ICD-10. Last updated 4/2/2024. Available at:
<https://www.cms.gov/medicare/coverage/determination-process/basics/lab-ncds-icd-10>.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
6/2024	New Medicare Advantage medical policy