

# Medicare Medical Policy

## Laboratory Testing Services

MEDICARE MEDICAL POLICY NUMBER: 456

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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
<p><b>NOTES:</b></p> <ul style="list-style-type: none"><li>• <b>*If a test, condition or indication is addressed by another Plan medical policy please use the more specific policy.</b></li><li>• <i>Title XVIII of the Social Security Act, Section 1862(a)(1)(A)</i> states " ...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury...".</li><li>• CMS maintains a longstanding policy that "tests that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered unless explicitly authorized by statute". However, the following Medicare coverage criteria for diagnostic laboratory services may not be considered "not fully established" under CFR § 422.101(6)(i)(A) <b>for specific tests and/or indications.</b><sup>1</sup></li><li>• In the absence of fully established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the service area in which the testing is being performed, additional criteria may be needed to interpret or supplement these general coverage provisions in order to determine medical necessity consistently. An evidence review of peer-reviewed literature may be performed for medical necessity decision-making. These criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services <b>because the use of such additional criteria, based on peer-reviewed evidence, evaluate how test results are expected to improve diagnosis, improve patient management, change treatment decisions or improve health outcomes.</b> Specifically, the evaluation of available evidence aids in determining whether or not a test has established clinical utility and/or analytic validity.</li></ul>	

- Regardless of whether a formal medical policy is published by the Company for a particular laboratory testing service, all providers are expected to follow Medicare’s medical necessity requirements when rendering treatment to plan members, and utilization may be subject to audit and/or post payment data analysis.
- Scope of practice/scope of license is addressed in a separate reimbursement policy (see Cross References).

**Medical Necessity Criteria**

- I. For tests with a relevant national coverage determination (NCD), local coverage determination (LCD) and/or local article (LCA), compliance with these policies is required where applicable.<sup>2</sup>
  
- II. For tests which do **not** have an applicable NCD, LCD, or LCA, then **all** of the following must be met in order to be considered medically reasonable and necessary and eligible for coverage under Medicare:
  - A. The ordering **physician or other healthcare provider** meets **both** of the following requirements (a. and b.):
    1. They are treating the member for a specific medical problem, condition, or injury (e.g., they have furnished a consultation or have treated the member for a specific medical problem, condition, or injury); **and**
    2. The ordering provider has documented in the medical record how they plan to promptly use the test results to directly manage that condition for the member.<sup>3,4</sup>
  
  - B. The **member** has signs or symptoms of an illness, disease or condition related to the test performed (unless allowed by Medicare statute as a preventive service); **and**
  - C. The **test** must meet **all** of the following (a.-c.):
    1. Proven clinical utility and analytical validity related to the condition (this is expected in order for test results to be effectively used for the management of a specific medical problem), as determined by **any** of the following:
      - i. FDA approval/clearance; **OR**
      - ii. scientific validity established, with proven accuracy, precision, sensitivity, specificity, reproducibility of results) based on published, peer-reviewed prospective evidence.

	<ol style="list-style-type: none"> <li>2. Ordered and performed according to manufacturer’s intended indications and/or FDA-approved/cleared indications for use; <b>and</b></li> <li>3. Not duplicate or overlap clinical intent with other diagnostic services previously or currently being performed.</li> <li>4. Performed at a frequency that does not exceed medically reasonable and necessary expectations.</li> </ol>
<p><b>Not Medically Necessary Testing</b></p> <p><b>NOTE:</b> Many tests may provide valid or useful information; however, they may be “not covered” if they do not meet Medicare’s benefit and medical necessity requirements to be eligible for coverage.<sup>7</sup></p>	<ol style="list-style-type: none"> <li>III. For testing services <b>with</b> applicable NCD, LCD, or LCA, testing services are <b>not medically necessary</b> if any of the following apply (A, B, or C): <ol style="list-style-type: none"> <li>A. Medical necessity coverage criteria in the NCD, LCD, or LCA are not met; <b>or</b></li> <li>B. If claims are submitted without an ICD–10–CM code listed as ‘covered’ in the Medicare coverage policy<sup>5</sup>; <b>or</b></li> <li>C. Testing exceeds frequency expectations noted in the applicable NCD, LCD or LCA<sup>5</sup>.</li> </ol> </li> <li>IV. Testing services <b>without</b> fully established Medicare coverage criteria in an applicable NCD, LCD, or LCA may be considered <b>not medically necessary</b> on a national basis under <i>Title XVIII of the Social Security Act, Section 1862(a)(1)(A)</i> under <b>any</b> of the following circumstances: <ol style="list-style-type: none"> <li>A. Tests <b>not</b> ordered by a physician or other healthcare provider treating the member for a medical condition (this includes direct-to-consumer [DTC] or over-the-counter [OTC] tests, which are direct benefit exclusions in Medicare Advantage EOCs [exceptions may be made at plan discretion for COVID-19 tests]); <b>or</b></li> <li>B. Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims<sup>5</sup>; <b>or</b></li> <li>C. Tests that do not provide data that will be directly used in the management of a specific medical problem (i.e., tests which do not provide actionable data for treatment of the member’s medical condition or if test results do not provide information that will improve patient outcomes and/or change physician care and treatment of the patient)<sup>3,4</sup>; <b>or</b></li> <li>D. If claims are submitted without an ICD-10-CM code listed as 'covered' based on Company evidence review for the test in question; <b>or</b></li> </ol> </li> </ol>

- E. Tests deemed not medically reasonable and necessary for the diagnosis or treatment of an illness or injury, or tests excluded by Medicare statute, as determined by **any** of the following;<sup>5</sup>
- a. Tests performed in the absence of signs, symptoms, complaints, or personal history of disease or injury (including tests to determine risk for developing a disease or condition, and tests required by insurance companies, business establishments, government agencies, or other third parties).<sup>5</sup> These tests are considered screening<sup>6</sup>, ***unless*** explicitly authorized by statute and addressed by another policy [e.g., *Preventive Services*] as a covered screening service *Services*); **or**
  - b. Tests used to confirm a diagnosis or known information (testing in this situation would not meet Medicare’s statutory requirements for diagnostic testing coverage as they are not used in the management of a specific medical condition as required under the *Medicare Benefit Policy Manual, Ch. 15* and *CFR § 410.32*)<sup>7</sup>; **or**
  - c. Tests performed to measure the quality of a process, or tests performed to confirm the sample belongs to a particular member (testing in this situation would not meet Medicare’s “medically reasonable and necessary” statutory requirements for coverage as these tests are not used for diagnosis or treatment planning of an illness or injury as required under *Title XVIII of the Social Security Act, Section 1862(a)(1)(A)*)<sup>7</sup>; **or**
  - d. Tests without diagnosis specific indications (testing in this situation would not meet Medicare’s “medically reasonable and necessary” statutory requirements for coverage as these tests are not used for diagnosis or treatment planning of an illness or injury as required under *Title XVIII of the Social Security Act, Section 1862(a)(1)(A)*); **or**
  - e. Tests identified as investigational or experimental by available literature and/or the literature supplied by the developer and are not a part of a clinical trial (if applicable) (testing in this situation would not meet Medicare’s “medically reasonable and necessary” statutory requirements for coverage because experimental services are considered ‘not medically necessary’ according to *Medicare Claims Processing Manual, Ch. 23, §30.A*); **or**

	F. Testing exceeds medically reasonable and necessary frequency expectations based on Company evidence review for the test in question.
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**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

### Medical Policies

- [Genetic and Molecular Testing](#), MP317

### Reimbursement Policies

- [Preventive Services](#), RP27
- [Scope of License, Scope of Practice, and Provider Qualifications](#), RP8

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

## POLICY GUIDELINES

### DOCUMENTATION REQUIREMENTS

In order to review for medical necessity, the following documentation **must** be provided. If any of these items are not submitted, the review may be delayed and the decision outcome could be affected:

- Test name;
- Name and location of laboratory that performed (or will be performing) the test;
- Clinical notes should include the following:
  - Condition or suspected condition
  - Documentation supporting the member was advised of tests being ordered
  - What information test results are expected to provide (e.g., make diagnosis, determine medication therapy(ies), etc.)
  - Signs/symptoms/prior test results related to reason for genetic testing
  - Family history, if applicable
  - How test results will impact clinical decision making.

Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.<sup>5</sup>

### MEDICARE COVERAGE AND MEDICAL NECESSITY BACKGROUND

In order for a laboratory service (including genetic and molecular testing) to be considered for coverage, Medicare requires that the test in question meet **all** of the following:

- Not be excluded from coverage by statute, regulation, National Coverage Determination, (NCD), or Local Coverage Determination (LCD);<sup>8</sup>
- Be ordered by a physician or practitioner who is treating the beneficiary;<sup>3,4</sup>
- Provide data that will be directly used in the management of a beneficiary's specific medical problem;<sup>3,4</sup>
- Be considered medically reasonable and necessary, as required per the Social Security Act, §1862(a)(1)(A). This means the service must be considered reasonable and necessary in the

diagnosis or treatment of an illness or injury, or to rule out or confirm a suspected diagnosis because the patient has signs and/or symptoms.<sup>9,10</sup>

- This also means services deemed not medically necessary for any reason (including lack of safety and efficacy for investigational services) are also non-covered.<sup>11</sup>

Specific health care services must fit into one of these benefit categories, and not be otherwise excluded, to be eligible for coverage under the Medicare program.<sup>12</sup>

The Act does not contain a comprehensive list of specific items or services eligible for Medicare coverage. Rather, it lists categories of items and services, and vests in the Secretary the authority to make determinations about which specific items and services within these categories can be covered under the Medicare program. That is, the Act allows Medicare to cover medical devices, surgical procedures, and diagnostic services, but generally does not identify specific covered or excluded items or services.<sup>12</sup>

### **Screening vs. Diagnostic**

Under Medicare, 'screening' is testing performed "in the absence of signs, symptoms, complaints, personal history of disease, or injury." Screening services are generally considered **not** medically necessary and not eligible for coverage, **except** when explicitly covered by Medicare as a preventive service. In contrast, 'diagnostic' testing is testing performed to rule out or to confirm a suspected diagnosis because of a sign and/or symptom in the member.<sup>6</sup> In these cases, the sign or symptom should be used to explain the reason for the test.

Laboratory tests which are covered by the Medicare program for screening purposes are listed as preventive services in section 42 CFR 411.15(a)(1)<sup>13</sup> and the CMS Preventive Services tool<sup>14</sup>.

### **Nationally Non-Covered Indications**

*Title XVIII of the Social Security Act, Section 1862(a)(1)(A)* states " ...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..."

CMS maintains a longstanding policy that "tests that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered unless explicitly authorized by statute."

### **Medically Reasonable and Necessary Guidelines**

In addition to the above general Medicare requirements, under Chapter 13 of the Medicare Program Integrity Manual, Medicare allows contractors to consider a service "reasonable and necessary" when the service is appropriate for the member's condition. This includes appropriateness in duration, frequency, and that the service is furnished in accordance with accepted standards of medical practice for the condition, furnished in a setting appropriate to the medical needs and condition, ordered and furnished by qualified personnel, that the service meets, but does not exceed, the medical need; and is at least as beneficial as an existing and available medically appropriate alternative.<sup>15</sup>

Medicare coverage criteria for diagnostic laboratory services may not be considered “not fully established” under CFR § 422.101(6)(i)(A) for specific tests and/or indications. In the absence of fully established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the service area in which the testing is being performed, evidence-based criteria may be used for medical necessity decision-making. Reviews of “reasonable and necessary” include frequency utilization, to ensure the service is furnished in a manner appropriate to the condition, and meets but does not exceed the medical need.

All providers are expected to follow Medicare’s medical necessity requirements when rendering treatment to plan members, and utilization may be subject to audit and/or post payment data analysis.

## 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

Regardless of whether a formal medical, reimbursement or coding policy is published by the Company for a particular laboratory testing service, all standard coding and billing rules apply and must be abided by. All providers are expected to follow Medicare’s medical necessity requirements when rendering treatment to plan members, and utilization may be subject to audit.

CODES*		
CPT	None	
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. Code of Federal Regulations (CFR). 42 CFR § 422.101(6)(i)(A). Requirements relating to basic benefits. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-C/section-422.101>. Accessed 2/13/2026.
2. Centers for Medicare and Medicaid Services (CMS). Medicare Managed Care Manual, Ch. 4 - Benefits and Beneficiary Protections, §10.2 - Basic Rule. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf>. Accessed 2/13/2026.
3. 42 CFR §410.32(a). <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.32>. Accessed 2/13/2026.
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5. Federal Register / Vol. 66, No. 226 / Friday, November 23, 2001. <https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/downloads/lab2.pdf>. Accessed 2/13/2026.
6. Centers for Medicare and Medicaid Services (CMS). Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, §120.1 - Negotiated Rulemaking Implementation (See section titled, "Clarification of the Use of the Term “Screening” or “Screen”"). <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf>. Accessed 2/13/2026.
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10. CMS. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §20 - Services Not Reasonable and Necessary. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c16.pdf>. Accessed 2/13/2026.
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12. Federal Register / Vol. 68, No. 187 / Friday, September 26, 2003. <https://www.cms.gov/medicare/coverage/determinationprocess/downloads/fr09262003.pdf>. Accessed 2/13/2026.
13. 42 CFR 411.15(a)(1). Particular services excluded from coverage. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-411/subpart-A/section-411.15>. Accessed 2/13/2026.
14. CMS Preventive Services tool. <https://www.cms.gov/medicare/prevention/prevntiongeninfo/medicare-preventive-services/mps-quickreferencechart-1.html>. Accessed 2/13/2026.

15. CMS. Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, §13.5.4 - Reasonable and Necessary Provision in an LCD. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf>. Accessed 2/13/2026.

## ***POLICY REVISION HISTORY***

<b>DATE</b>	<b>REVISION SUMMARY</b>
6/2026	New Medicare Advantage medical policy