Medicare: Hierarchy for Applying Coverage Decisions for Laboratory Testing

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Procedures addressed

The inclusion of any procedure code in this table does not imply that the code is under management or requires prior authorization. Refer to the specific Health Plan's procedure code list for management requirements.

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Note  *Generally defined as codes that include “DNA”, “RNA”, “nucleic acid”, “genotype”, “phenotype” or related language in the code description.

Medicare background

Medicare Administrative Contractors (MACs)

eviCore healthcare follows Medicare rules when applying coverage decisions for laboratory testing under Medicare Advantage plans. Medicare has devised a system where various contractors, called Medicare Administrative Contractors (MAC), set coverage policy for various jurisdictions, which cover specific states. A complete list of MACs by state can be found here.

National Coverage Determinations (NCDs)

NCDs are developed by Centers for Medicare and Medicaid Services (CMS). They apply to Medicare coverage nationwide for a specific medical service, procedure, or device.
Local Coverage Determinations (LCDs)

LCDs are written by the different MACs. LCDs outline whether a certain medical service, procedure, or device is covered. However, the coverage guidelines outlined in LCDs are enforceable only in the states under the specific MAC’s jurisdiction.

- In the case of independent laboratories that perform their own billing, the MAC jurisdiction will be based on the state in which the performing lab is located.*
- In the case of a reference lab, the MAC jurisdiction will be based on the state in which the billing is performed.†
- For purposes of prior authorization case reviews, eviCore healthcare will ask a series of questions to determine if there is a reference lab relationship that would impact jurisdiction. If a reference lab relationship is not disclosed or cannot be determined with the information provided, eviCore healthcare will default to the state in which the performing laboratory is located to determine MAC jurisdiction.

Articles

Medicare contractors may issue Medicare Coverage Articles. Articles are non-LCD documents that contain coverage statements, coding guidelines or medical review related billing or claims considerations. They may include specific coding instructions and/or clarify existing medical review policies. Articles typically include guidance by ICD10 codes only; however, Articles may sometimes include verbiage containing test-specific medical review coverage criteria. Articles are posted, along with LCDs, in the Medicare Coverage Database.²

MolDX program

Medicare contractors may choose to create their own LCDs or to defer to the MolDX® Program administered by the Palmetto GBA MAC for the development of LCDs for genetic tests.‡ ¹ In addition to Palmetto GBA, the following contractors have implemented the MolDX Program’s coverage criteria in their LCDs for genetic tests: Noridian, CGS, and Wisconsin Physicians Service (WPS).³ ⁴ ⁵

The MolDX Program maintains a list of tests that can be considered for coverage if the patient meets either test-specific criteria (if available) or general Medicare coverage criteria of a reasonable and necessary service. Inclusion on this list is not a guarantee of coverage. A complete list of MolDX “covered” tests is available here. The MolDX Program also maintains a list of tests that are excluded from coverage. A list of MolDX excluded tests and associated articles is available here.

Reasonable and necessary service

Medicare defines services as reasonable and necessary if they lead to “the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” § ⁶
Medicare Criteria Hierarchy

When performing case reviews for genetic tests for Medicare members, eviCore will employ the following strategy:

- Identify any NCDs that apply to the test by searching the Medicare coverage database [here](#);
  - When applying an NCD, verify that the effective date of the NCD includes the date of service of the test.
  - If an applicable NCD is identified, then the test-specific coverage criteria from the NCD along with a determination that the service is reasonable and necessary (as described below), will be applied.

- If no NCD exists, identify any LCDs that apply to the test by searching the Medicare coverage database [here](#);
  - To identify the applicable LCD, first look at the LCDs established by the appropriate MAC.
  - In the case of independent laboratories that perform their own billing, the MAC jurisdiction will be based on the state in which the performing lab is located.
  - In the case of a reference lab, the MAC jurisdiction will be the state in which the billing is performed.
    - For purposes of prior authorization case reviews, eviCore healthcare will ask a series of questions to determine if there is a reference lab relationship that would impact jurisdiction. If a reference lab relationship is not disclosed or cannot be determined with the information provided, eviCore healthcare will default to the state in which the performing laboratory is located to determine MAC jurisdiction.
    - If there are no appropriate LCDs in the MAC jurisdiction, determine if the MAC has an existing relationship with Palmetto GBA and has implemented the MolDX criteria. If the MAC defers to the MolDX Program, then identify any policies from the MolIDX Program that apply to the test.
      - Under the MolIDX Program, “covered” tests can be considered for coverage if the patient meets either test-specific criteria including any ICD10 code restrictions (if available) or general Medicare coverage criteria of a reasonable and necessary service. Inclusion on this list is not a guarantee of coverage. A complete list of MolIDX “covered” tests is available [here](#).
      - The MolIDX Program also maintains a list of tests that are excluded from coverage because they do not meet a Medicare statutory benefit. A list of MolIDX excluded tests and associated articles is available [here](#). If the test is listed as excluded or not covered on an applicable article or LCD, this testing will not be covered for MACs that defer to MolIDX.
When applying an LCD, verify that the effective date of the LCD includes the date of service of the test.

If an applicable LCD is identified, then the test-specific coverage criteria, from the LCD along with a determination that the service is reasonable and necessary (as described below), will be applied.

- If there are no applicable LCDs, or the applicable LCD does not include test-specific coverage criteria, then any applicable Article(s) containing test-specific coverage criteria will be applied.
- If the test is listed on an Article or LCD as being not covered, the testing will not be covered.
- If there are no applicable LCDs or Articles, or the applicable LCD or Article does not include test-specific coverage criteria, then eviCore evidence-based criteria for diagnostic testing will be applied.**8

In addition to eviCore diagnostic testing criteria, patient-specific coverage approval or denial decisions may be made in accordance with the Medicare requirement that a service be reasonable and necessary for the treatment of an injury or illness. To determine whether a service is reasonable and necessary, specific criteria will be applied that may include, but are not limited to, the following:1,9,10

- The beneficiary must display clinical features of an associated disease, noting that coverage of molecular testing for carrier status or family studies (often referred to as pre-symptomatic or pre-disposition testing) is considered screening and is statutorily excluded from coverage; and
- The result of the test will directly impact the treatment being delivered to the beneficiary; and
- If, after history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain, then such testing can be considered for coverage.

- If application of eviCore criteria has resulted in an “investigational/experimental” coverage determination for the test(s), but there is an applicable Article containing specific guidance including only ICD10 diagnosis codes, then that Article should be applied.
- If application of eviCore criteria has resulted in a “not medically necessary” coverage determination for the test(s) for a member, that decision will not be altered based on an Article containing guidance including only ICD10 diagnosis codes.

References

1. Molecular Diagnostics Program. Coverage, coding, and pricing standards and requirements (M00106). Available at:
$File/MolDX_Manual.pdf

2. Medicare Coverage Articles. Available at: https://med.noridianmedicare.com/web/jea/policies/coverage-articles


5. WPS GHA Announces MolDX Expansion to J5 and J8. Available at: https://www.wpsgha.com/wps/portal/mac/site/policies/guides-and-resources/moldx-resources/!ut/p/z0jY7LTsMwEEV_pSy8jGZIoXRbUFFUJYIVCt4g1zHOgONxbRdavp60C4RQQSzvnc5IKFE6dUbWZWJvXJfPpSp_uqmlXnc6zvygZx0dw-TJfz-hqXJoA_rqwurq4PHwoy3PTWJBB5b4g_8zQKh3Z74d0GNPLZiMXIDX7bHYZ2veQJsfg88R46yj1AnsejMCvu7-4R7HTXLulzqRC-a6IJveE2ajM6DOy63ffiv1KZA-ICj52JAgM70mSSwFMYgT8x4VWu99OPunL27BN5fJci/#


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* Per Section 50.5 of the Medicare Claims Processing Manual, Chapter 16 (Rev. 4000, 03-16-18), "jurisdiction of payment requests for laboratory services furnished by an independent lab … lies with the A/B MAC (B) serving the area in which the laboratory test is performed. Jurisdiction is not affected by whether or not the independent laboratory uses a central billing office and whether or not the laboratory provides
services to customers outside its A/B MAC (B)’s service area. The location where the independent laboratory performed the test determines the appropriate billing jurisdiction.”

† Per Section 50.5.1 of the Medicare Claims Processing Manual, Chapter 16 (Rev. 4000, 03-16-18), Regardless of whether the laboratory that bills Medicare is the referring or reference laboratory, the laboratory that does the billing may bill only the A/B MAC (B) that services the jurisdiction in which the billing laboratory is physically located. The location of the draw station, when a separate draw station is employed, never determines claims filing jurisdiction.

‡ Per Chapter 13 of Medicare Program Integrity Manual “Contractors use Medicare policies in the form of regulations, NCDs, coverage provisions in interpretive manuals, and LCDs to apply the provisions of the (Social Security) Act.”

§ Per Chapter 3 of the Medicare Program Integrity Manual (Rev. 825, 09-21-18), “CMS issues national coverage determinations (NCDs) that specify whether certain items, services, procedures or technologies are reasonable and necessary under §1862(a) (1) (A) of the Act. In the absence of an NCD, Medicare contractors are responsible for determining whether services are reasonable and necessary. If no local coverage determination (LCD) exists for a particular item or service, the MACs, CERT, Recovery Auditors, and ZPICs shall consider an item or service to be reasonable and necessary if the item or service meets the following criteria: It is safe and effective; It is not experimental or investigational; and It is appropriate, including the duration and frequency in terms of whether the service or item is: Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member…”

** Per section 90.5 of the Medicare Managed Care Manual, Chapter 4 (Rev. 121, 04-22-16), “In coverage situations where there is no NCD, LCD, or guidance on coverage in original Medicare manuals, an MAO (Medicare Advantage Organization) may adopt the coverage policies of other MAOs in its service area. However, if the MAO decides not to use coverage policies of other MAOs in its service area, the MAO: Must make its own coverage determination; …Must provide CMS an objective evidence-based rationale relying on authoritative evidence…”