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.

Procedures addressed by this guideline	Procedure codes
Molecular Pathology	81105 - 81479
Molecular Multianalyte Assays with Algorithmic Analyses (MAAA)	81490 – 81599; Molecular* administrative MAAA codes (ending in M)
Molecular Proprietary Laboratory Analyses (PLA)	Molecular* PLA codes (ending in U)
Molecular Infectious Testing	Molecular tests* within range 87149 – 87912, G0476, 0500T
Molecular HCPCS Codes	S3800 - S3870 G0452, G9143 U0001-U0004
Molecular Cytopathology Procedures (Flow Cytometry, In Situ Hybridization)	88120 - 88121 88182 - 88199
Cytogenetics	88230 - 88299
Molecular Surgical Pathology Procedures (Immunohistochemistry, In Situ Hybridization)	88341 - 88344 88360 - 88361 88364 – 88377 88380 - 88388
Other Molecular Laboratory Codes	84999 86152 86153

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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

eviCore healthcare follows Medicare rules when applying coverage decisions for laboratory testing under Medicare Advantage plans.

Medicare Administrative Contractors (MACs)

Medicare has devised a system where contractors, called Medicare Administrative Contractors (MAC), perform various administrative duties including processing claims and establishing coverage policy where none exists nationally. MACs are awarded geographic jurisdictions, which cover specific states. A complete list of MACs by state can be found here.

The laboratory has the responsibility for determining which MAC has jurisdiction over their services. Medicare provides detailed guidance in their Claims Processing Manual, Chapter 16, Laboratory Services, located here. While there are nuances and exceptions, CMS makes the following general statements:[1]

- “Jurisdiction of payment requests for laboratory services furnished by an independent laboratory, except where indicated in §50.5.1 and §50.5.2, 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.”
- When there are two laboratories involved due to a referral/reference lab relationship: “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.”

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 the criteria under which 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. LCDs are posted in the Medicare Coverage Database.[2]

Local Coverage Articles (LCAs)

Medicare contractors may issue LCAs, which are non-LCD documents that may include specific coding instructions, clarify existing medical review policies, and/or define ICD10 codes that support the medical policy. LCAs are posted, along with LCDs, in the Medicare Coverage Database.[2]

MolDX Program

Medicare contractors may choose to implement policy created by the MolDX® Program administered by the Palmetto GBA MAC for laboratory tests in scope for the MolDX program, including molecular diagnostics and molecular pathology services and further defined in Local Coverage Article A56853.[3] In addition to Palmetto GBA, the following contractors have implemented the MolDX Program: Noridian Healthcare Solutions, CGS Administrators, and Wisconsin Physicians Service (WPS) Government Health Administrators.[4-6]

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." § [7]

Medicare Criteria Hierarchy

When making medical necessity determinations for Medicare members, eviCore will employ the following strategy for both utilization management case reviews and automated claim edit application:

- Coverable procedure codes will be identified for Medicare using all applicable available guidance, including but not limited to the Physician Fee Schedule Relative Value File, Alpha Numeric HCPCS File, and local guidance. If any source indicates a procedure code is not coverable, that source will take priority and the procedure code will be denied through case review or claims processing.
- If the procedure code is eligible for coverage, apply criteria and/or claims rules from any applicable NCDs identified via the Medicare coverage database (located here);
    - An NCD will only be applicable when the effective date of the NCD includes the date of service of the test.
- If no NCD exists:
    - Determine which MAC has jurisdiction
        - For purposes of prior authorization case reviews, the site of service is submitted with the case. eviCore will use the location of the submitted laboratory unless a reference lab relationship is disclosed which suggests that the location of an alternate billing laboratory should be used.

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    - When processing claims, the appropriate MAC jurisdiction for applying policy is provided by the Health Plan.

  - Apply criteria and/or claims from applicable LCDs and LCAs identified via the Medicare coverage database (located here) based on the MAC with jurisdiction.

    - An LCD or LCA will only be applicable when the effective date of the LCD or LCA includes the date of service of the test.
    - If an applicable LCD or LCA with test-specific criteria is identified, then the test-specific coverage criteria will be applied through case review or claim edits.
    - If the test is listed within an LCD or LCA as being not covered, the testing will not be covered.

- If there are no applicable LCDs or LCAs, or the applicable LCD or LCA does not include test-specific coverage criteria, then eviCore evidence-based criteria for diagnostic testing will be applied through case review or claim edits.**[8]

  - If application of eviCore criteria results in an "investigational/experimental" coverage determination for the test(s), but there is an applicable LCA including only ICD10 diagnosis codes, then that LCA will be applied.
  - When an LCD or LCA includes only ICD10 diagnosis codes intended to inform coverage without any additional criteria, but a case review is performed, all information provided will be used in making a coverage determination based on the full content of the LCD or LCA and eviCore evidence based criteria – not simply the diagnosis codes. As a result, it is possible that a service will be found not medically necessary even if submitted with coverable ICD10 diagnosis codes.

  - In addition to eviCore 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:

    - The beneficiary must display clinical features of an associated disease. For example, coverage of testing for risk assessment, 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, and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain, then such testing can be considered for coverage.

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References

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8. Medicare managed care manual. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326.html

‡ Per Chapter 13 of Medicare Program Integrity Manual "An LCD, as defined in §1869(f)(2)(B) of the Social Security Act (SSA), is a determination by a Medicare Administrative Contractor (MAC) respecting whether or not a particular item or service is covered on a contractor–wide basis in accordance with section 1862(a)(1)(A) of the Act." [6]

§ 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

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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…" [7]

** 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…" [8]

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