Genetic Test Coverage and Payment Guide for Medicare Advantage

A definitive guide to help Medicare Advantage plans understand coverage and payment rules for genetic testing and other laboratory services

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CONCERT GENETICS

Coverage & Payment Challenges are Compounded for Medicare

Health plans and labs alike struggle to accurately determine coverage, coding and pricing of genetic tests and other laboratory services. With differing rules for Medicare Advantage (MA) and Original Medicare plans, these tasks are even more challenging when serving Medicare beneficiaries. This paper aims to provide definitive guidance on the coverage and payment rules for Medicare Advantage plans as it relates to the complex and rapidly evolving world of laboratory services.

Concert Genetics enlisted leading experts to address areas of industry confusion around Medicare coverage, pricing and billing. Key conclusions and their supporting regulation references are summarized below.

Medicare Advantage Coverage, Pricing & Coding Guidance

Coverage	• **MA plans must provide the same benefits as Original Medicare,** as published in National Coverage Determinations (NCDs) and the relevant Local Coverage Determinations (LCDs). When Original Medicare coverage criteria is not fully established, MA plans may create and make public additional evidence-supported coverage criteria. For laboratory tests, the location where the test is performed determines which jurisdiction's LCDs apply. • **MA plans may provide additional benefits beyond Original Medicare,** as contracted with labs and published in their medical policies. • **MA plans may use commercial practices to manage utilization**, but may only use prior authorization to confirm the service is medically necessary. • **MA plans must establish a Utilization Review Committee** that annually reviews policies to ensure compliance with Medicare coverage requirements.
Pricing	• **MA plans may reimburse contracted labs ("in-network" or "par") at the rates in their contracts.** • **MA plans are expected to reimburse all other labs ("out-of-network" or "non-par") at least Original Medicare rates, following the CMS Clinical Lab Fee Schedule.**
Coding	• **MA plans may create their own coding, billing and payment procedures that apply to both contracted and non-contracted labs/providers.** • **MA plans may use commercial practices to manage appropriate coding, like claim editing solutions.**

Coverage

Medicare Advantage plans must cover the same benefits as Original Medicare.[1] Accordingly, every MA plan:

- Must cover genetic testing and other laboratory services as published in National Coverage Determinations (NCDs).[2]
- Must cover genetic testing and other laboratory services as published in Local Coverage Determinations (LCDs) for labs that performed the tests within the associated Medicare jurisdiction.[3] For laboratory services, jurisdiction (and which LCDs apply) is determined by the location where the test is performed.[4] Labs that perform genetic testing services often

only have a few locations nationwide. This is different from physician services that are performed in-person in thousands of locations. So, it is common for the genetic testing lab's jurisdiction to be different from the Medicare beneficiary's residence jurisdiction–and for it to be more difficult to determine which LCDs apply.

MA plans are allowed to augment Original Medicare in a number of ways, including:

- Covering more services than are required by NCDs and LCDs.[5]
- Creating additional coverage criteria when Original Medicare's coverage criteria are not fully established.[6]
- Using prior authorization to manage utilization,[7] providing: it is only used to establish medical necessity,[8] it is consistent with Original Medicare's coverage requirements, and its policies are reviewed annually for compliance by a Utilization Management Committee.[9]

Pricing

MA plans are allowed to negotiate their own pricing/fee schedules with their contracted labs/providers. With non-contracted labs/providers, MA plans are expected to pay at least the Original Medicare rate (per the CLFS).[10]

Coding

MA plans may create their own coding, billing and payment procedures that apply to both contracted and non-contracted labs/providers.[11]

Accordingly, MA plans are not required to adopt or comply with the coding, billing or payment provisions that are published by CMS (National Correct Coding Initiative) or Medicare Administrative Contractors (LCDs, Billing & Coding Articles, and other directions).

MA plans may use any tools they wish to help them manage and enforce their coding, billing and payment rules. For example, they may utilize claim editing, anti-fraud and recovery solutions.

References

1. "Medicare Managed Care Manual," CMS.gov, Internet-only Manuals, Publication #100-16, Chapter 4, Section 10.2 (page 6).
   https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c04.pdf
   > "An MAO [Medicare Advantage Organization] offering an MA plan must provide enrollees in that plan with all Part A and Part B original Medicare services...."

2. "Medicare Managed Care Manual," CMS.gov, Internet-only Manuals, Publication #100-16, Chapter 4, Section 90.1 (page 65).
   https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c04.pdf
   > "As discussed in section 10.2 of this chapter, an item or service classified as an original Medicare benefit must be covered by every MA plan if... It is covered by CMS' national coverage determinations...."

3. "Medicare Managed Care Manual," CMS.gov, Internet-only Manuals, Publication #100-16, Chapter 4, Section 90.1 (page 65).
   https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c04.pdf
   > "As discussed in section 10.2 of this chapter, an item or service classified as an original Medicare benefit must be covered by every MA plan if... It is covered by written coverage decisions of local Medicare Administrative Contractors (MACs) with jurisdiction for claims in the geographic area in which services are covered under the MA plan...."

4. "Medicare Claims Processing Manual," CMS.gov, Internet-only Manuals, Publication #100-04, Chapter 16 - Laboratory Services, Section 50.5 - Jurisdiction of Laboratory Claims (page 35).
   https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c16.pdf
   > "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 50.appropriate billing jurisdiction. Therefore, even if the sample originates in a different jurisdiction from where the sample is being tested, the claim would still be filed in the jurisdiction where the test was performed."

5. "Medicare Managed Care Manual," CMS.gov, Internet-only Manuals, Publication #100-16, Chapter 4, Section 10.2 (page 7).
   https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c04.pdf
   > "While an MA plan may offer additional coverage as a supplemental benefit, it may not limit the original Medicare coverage."

6. "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," Federal Register, Vol. 88, No. 70, Wednesday, April 12, 2023, Rules and Regulations, pages 22121-22122.
   https://www.govinfo.gov/content/pkg/FR-2023-04-12/pdf/2023-07115.pdf
   > "...[W]hen coverage criteria are not fully established in Medicare statute, regulation, NCD, or LCD, MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature.... [T]he MA organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services."

7. “Medicare Managed Care Manual,” CMS.gov, Internet-only Manuals, Publication #100-16, Chapter 1, Section 20.2 (page 3).
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c01.pdf
“CCPs may use mechanisms to control enrollee utilization of services. Mechanisms may include requiring referrals from a gatekeeper (usually the enrollee’s primary care provider (PCP)) or prior authorization for an enrollee to receive certain covered services (42 CFR 422.4(a)(1)(ii)).”

8. “Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,” Federal Register, Vol. 88, No. 70, Wednesday, April 12, 2023, Rules and Regulations, page 22122.
https://www.govinfo.gov/content/pkg/FR-2023-04-12/pdf/2023-07115.pdf
“…[P]rior authorization policies for coordinated care plans may only be used to confirm the presence of diagnoses or other medical criteria and/or ensure that an item or service is medically necessary based on standards specified in this rule.”

9. “Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,” Federal Register, Vol. 88, No. 70, Wednesday, April 12, 2023, Rules and Regulations, page 22122.
https://www.govinfo.gov/content/pkg/FR-2023-04-12/pdf/2023-07115.pdf
“…[A]ll MA plans [must] establish a Utilization Management Committee to review all utilization management, including prior authorization, policies annually and ensure they are consistent with the coverage requirements, including current, traditional Medicare’s national and local coverage decisions and guidelines.”

10. “Medicare Managed Care Manual,” CMS.gov, Internet-only Manuals, Publication #100-16, Chapter 6, Section 100 (page 22).
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c06.pdf
“Consistent with §1852(a)(2) and §1852(k)(1) of the Social Security Act, non-contract providers must accept as payment in full payment amounts applicable in Original Medicare. Thus, this provision of law imposes a cap on payment to non-contract providers of provider payment amounts plus beneficiary cost-sharing amounts applicable in Original Medicare, and ensures that non-contract providers not balance bill MA plan enrollees for other than MA plan cost-sharing amounts…. In cases where the MA organization has not arranged for the services, if the noncontract provider’s bill is less than the Original Medicare amount, the MA organization is only required to pay the billed amount…. In addition, under Federal law, non-contract providers are subject to penalties if they accept more than Original Medicare amounts.”

11. “Medicare Managed Care Manual,” CMS.gov, Internet-only Manuals, Publication #100-16, Chapter 4, Section 10.2 (page 8).
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c04.pdf
“MA plans need not follow original Medicare claims processing procedures. MA plans may create their own billing and payment procedures as long as providers – whether contracted or not – are paid accurately, timely and with an audit trail.”