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Genetic testing: What Medicare will and will not cover

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In a report as part of the work plan related to Medicare Part B payments for laboratory services, the U.S. Department of Health and Human Services Office of Inspector General (OIG) noted a 230% increase in the number of paid genetic tests for calendar years 2016 through 2019.[1] The report states that even though there are legitimate reasons for an increase in testing, it is an area of concern for potential fraud and abuse.

Genetic testing analyzes changes in DNA, which provides the instructions for building proteins necessary for an individual's survival.[2] The tests may look for changes in genes, chromosomes, or the level of certain proteins due to changes in DNA. There are many reasons for performing the service, including screening for treatable conditions in newborns, determining the presence of a genetic disease that can be passed on to one's children, an individual's risk of developing a disease, diagnosis of a genetic condition, and guiding medical treatment or the prescribing dosage of planned therapy.

While any of these reasons for performing genetic testing are standard medical practice, few of them meet the Medicare requirement to cover services that are necessary to diagnose or treat an illness or injury.[3] The OIG specifically stated in their report that genetic tests used for predictive purposes would not be a covered service. Testing for the presence of disease or the risk of disease without clinical signs or symptoms is generally not covered by the Medicare program, except in a few limited circumstances. It may be difficult for clinical staff to understand even when there is strong medical evidence of the benefit of such testing, the service cannot be billed to Medicare.

Laboratory requirements for coverage

As with any diagnostic laboratory service, genetic testing must meet the minimum requirements for coverage of laboratory services:

- Test must be ordered by the physician treating the patient.
- Test results should be used for management of a specific medical condition.
- The provider must maintain documentation to support the medical necessity of the service.[4]

Failure to meet these requirements would be a red flag during a compliance review, suggesting the need for further auditing and possible monitoring of the service.

Specific coverage indications and limitations for laboratory services are mentioned in several manuals

maintained by the Centers for Medicare & Medicaid Services. Chapter 15 of the *Medicare Benefit Policy Manual* ("Covered Medical and Other Health Services") discusses the general requirements for diagnostic services in section 80.

Laboratory services are defined as:

". . . the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition."[5]

Coverage for lab tests related to the prevention of disease is very limited. Chapter 18 ("Preventive and Screening Services") of the *Medicare Claims Processing Manual* discusses the preventive and screening services covered by the Medicare program. Diagnostic screening laboratory tests are covered for Pap smears for women with certain conditions, prostate-specific antigen for men at a limited frequency, and fecal-occult blood test as part of screening for colorectal cancer. The use of genetic testing for colorectal is not included as part of the covered services for screening.[6]

Chapter 6, section 9 of the *Medicare Program Integrity Manual* ("Medicare Contractor Medical Review Guidelines for Specific Services") provides guidance for the medical review of diagnostic laboratory tests by Medicare contractors.[7] It discusses requirements related to acceptable orders for diagnostic laboratory services on a signed and unsigned requisition for services. For the unsigned document, the medical record must support the provider's intent to order the specific test, such as an entry to "check labs" or "repeat urine." Verbal orders require both the treating providers or their staff, and the laboratory staff to document the telephone call in their medical records. Electronic health records (EHRs) have decreased the risk in ordering laboratory services; however, situations may still exist that warrant further review, such as calls to the laboratory to add a test to specimens already sent to the facility.