

Genetic Tests and Medicare: Coverage and Oversight

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From coast to coast, SMPs are hearing concerns about Medicare coverage for [genetic testing](#). In New Jersey, Charles Clarkson has seen an explosion of ads for preventive genetic testing. In Wyoming, Sandy Goodman heard from a beneficiary who received a cold call from a Florida company that offered to send a kit containing a genetic test to screen for cancer. Medicare, the beneficiary was told, would pay for it. In Arkansas, Tennessee, and Utah, insurance agents have contacted SMPs to ask if efforts to recruit them to administer cheek swabs to seniors are legitimate. Agents in Arkansas reportedly said they could earn up to \$500 per swab for doing their part “to connect people with life-saving genetics testing,” as one [company](#) put it. Meanwhile, the California SMP has received reports about presentations given at senior centers where representatives advertise and offer free genetic tests to screen for cancer.

It probably should surprise no one that some Medicare beneficiaries are receptive to marketing ploys that combine serious claims about cancer with offers to detect the disease with free screenings before it strikes. The odds of getting cancer are relatively high. According to the [American Cancer Society](#) (ACS), one in three Americans are at risk of developing some type of cancer – bladder, breast, lung, ovarian, prostate, skin – during their lifetimes. One in five people are at risk of dying from it. But at the same time, the risk of inheriting a troublesome gene that leads to cancer is relatively low. It is well known that genetic changes, or mutations, play a part in cancer’s development, though only [five to 10 percent](#) of all cancers are strongly linked to an inherited gene mutation. The ACS notes that, “Most cancers start because of acquired gene mutations that happen during a person’s lifetime,” caused, for example, by tobacco use or exposure to sunlight.

Medicare Coverage for Genetic Tests

With so much interest in genetic tests as early warning systems for cancer, it makes sense that beneficiaries and others would wonder if Medicare covers genetic (or DNA) testing as a screening and prevention benefit. The answer, with one exception, is no. Although Medicare covers many genetic tests for diagnostic use, it only covers one genetic test to screen for cancer. Since October 2014, Medicare Part B has paid for the Cologuard™ test, manufactured by [Exact Sciences Corp.](#) of Madison, Wisconsin, to screen specifically for colorectal cancer. According to the [National Coverage Determination](#) (NCD) for colorectal cancer screening, Cologuard tests fecal DNA in a stool sample to detect signs, called molecular markers or [biomarkers](#), of altered DNA that show up in cells shed into the large bowel by cancerous and premalignant

Companion Article

For more information, read [Genetic Testing Fraud: An Enforcement Perspective](#) by Jennifer Trussell.

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growths. Medicare covers the test once every three years for beneficiaries between ages 50 and 85 who have no symptoms of colorectal cancer and an average risk for developing it. As with other Medicare-covered screening tests, Part B pays 100 percent of the approved amount.

While Medicare strictly limits coverage for genetic screening tests, it does cover many genetic tests that meet the criteria for diagnostic tests and are used to treat cancer and other medical conditions. Examples include tests developed by [Quest Diagnostics](#) that reveal molecular changes (including gene mutations) in cancerous tumors specific to an individual. The test results can help oncologists identify targeted therapies for rare cancers. Medicare also covers genetic testing for the BRCA1 and BRCA2 genes for patients suspected of hereditary breast and/or ovarian cancer syndromes. Mutations in these two “tumor suppressor” genes are associated with increased risk for some cancers. A widely adopted [Local Coverage Determination](#) (LCD) states that Medicare coverage depends on the beneficiary having signs or symptoms of breast, ovarian, pancreatic, or prostate cancer and meeting one of several other criteria. The LCD makes clear that current signs or symptoms of cancer must be present for Medicare to cover genetic testing for a known inherited mutation in a family. It says that, “Testing of an unaffected Medicare eligible individual or family member is not a covered Medicare benefit.”

Medicare also covers some genetic tests that assess an individual’s ability to metabolize certain drugs. Warfarin, a widely used blood thinning medication, is one example of Medicare’s coverage for “[pharmacogenomics](#).” The [NCD](#) for genetic tests to measure warfarin responsiveness explains that, “Pharmacogenomics denotes the study of how an individual’s genetic makeup, or genotype, affects the body’s response to drugs.” With warfarin, Medicare pays to test two genes as long as the test is part of a clinical study. Conditional coverage is fairly common while Medicare and its contractors are developing evidence of coverage for new diagnostic technologies. Although pharmacogenomic science is still in its infancy, the field is developing rapidly, with new tests appearing almost daily. It’s worth noting that the Food & Drug Administration (FDA) now includes pharmacogenomic information on the labels of some [200 drugs](#), including many used in oncology, psychiatry, and anesthesiology.

In 2012, Medicare had only 11 LCDs to address coverage criteria for genetic tests. Today there are dozens and dozens more Local Coverage Articles (LCAs) that the MACs (Medicare Administrative Contractors) issue to clarify their noncoverage policies. The pace at which the molecular diagnostic testing industry has evolved is staggering. In 2018, [researchers reported](#) that since the human genome was mapped in 2003, laboratories have developed more than 10,000 types of genetic tests. Currently, nearly 75,000 different branded tests have come to market, with about 10 new ones entering the marketplace daily. Prenatal tests account for the highest percentage of spending on genetic tests. Hereditary cancer tests come in second with approximately 30 percent of genetic test spending. Spending on pharmacogenomic testing was less than five percent of the total.

Oversight

What is CMS (the Centers for Medicare & Medicaid Services) doing to ensure that genetic testing meets Medicare’s statutory “reasonable and necessary” requirement? By and large, it has delegated responsibility to the A/B MACs, its Medicare Administrative Contractors. Significantly, [Palmetto GBA](#), the MAC for Alabama, the Carolinas, Georgia, Tennessee, Virginia, and West Virginia, introduced a program in 2011 called [MoIDX](#) (Molecular Diagnostics). Its

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purpose is to identify and establish coverage and reimbursement policies for [molecular diagnostic tests](#) (MDTs), including genetic tests. The program requires laboratories and manufacturers to register their MDTs and present data that

demonstrates the test's "clinical utility." One [industry observer](#) explained that clinical utility "involves the probability that test results will change provider behavior and improve patient outcomes." The A/B MACs for jurisdictions JE, JF, J5, J8, and J15 also use MoIDX. Thus, Medicare coverage for genetic tests in 28 states and three territories depends largely on evidence that the test meets the MoIDX's rigorous clinical utility standard. The A/B MACs for other jurisdictions use similar criteria with different procedures to assess the efficacy of genetic tests.

In a recent case, four MACs used the MoIDX clinical utility standard to withdraw coverage for a genetic test that its manufacturer promoted as a "rule out" test for stable, nondiabetic patients who showed new signs of coronary artery disease (CAD). An [LCD](#) issued by the MoIDX MACs said that, "Since initial coverage, the manufacturer has failed to demonstrate that testing resulted in improved patient outcomes or that testing changed physician management to result in improved patient outcomes." With news of the noncoverage for its Corus® CAD test, [CardioDx](#) of Redwood City, California, shut down its operations.

Guidance for SMPs

In the midst of rapid change, conditions are ripe for bad actors to take advantage of uncertainty and confusion. It's essential for SMPs to keep Medicare's core coverage rule for diagnostic tests in mind as they respond to beneficiaries, providers, and senior housing coordinators who want to know if genetic testing events are likely to be bogus. A [federal regulation](#) stresses that a treating physician must order genetic tests. It says:

"All diagnostic x-rays tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary."

SMPs are not, of course, in a position to go into the details about Medicare coverage policy for the wide array of genetic tests. There simply are too many of them. SMPs should, however, educate the public about Medicare's coverage (and noncoverage) rules for genetic tests in general. Remind folks that Medicare covers only one genetic screening test for colorectal cancer. Encourage those who have specific – or challenging – questions to use the [Medicare Coverage Database](#) to learn more about the coverage rules for genetic tests. SMPs can also refer to the MoIDX program manual section on excluded genetic tests. It lists several examples that do not qualify for Medicare coverage:

- Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law

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- Tests that confirm a diagnosis or known information
- Tests to determine risk for developing a disease or condition
- Tests performed to measure the quality of a process
- Tests without diagnosis-specific indications

The bottom line is that coverage criteria for genetic tests are strict. Those who contend that Medicare covers genetic tests to screen beneficiaries for cancer (other than colorectal cancer) are skating on very thin ice. SMPs should continue to report beneficiary complaints about genetic testing screening schemes as complex interactions to the OIG hotline through SIRS and refer insurance agents who have questions about participating in testing schemes to their state insurance commissioners. ●

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