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Independent Laboratory Settles Medical Necessity Allegations

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The Department of Justice (DOJ) recently announced a [\\$1.99 million False Claims Act \(FCA\) settlement](#) with GenomeDx Biosciences Corp. (“GenomeDx”), a laboratory headquartered in Vancouver, British Columbia with operations in San Diego. The matter arose as the result of a [qui tam case](#) brought by two former employees in September 2017.

The claims at issue relate to the Decipher® post-operative genetic test for prostate cancer patients (the “Decipher Test”), which reportedly is the only test offered by GenomeDx that is covered by Medicare. The Decipher Test is used to measure the activity of genes in prostate tumors to assess the risk of cancer recurrence. According to DOJ’s press release, GenomeDx submitted medically unnecessary claims to Medicare for the Decipher Test because patients did not have the specified risk factors required to qualify for reimbursement.

DOJ did not file its own complaint containing more specific allegations, but, according to the relators’ complaint, GenomeDx knowingly failed to comply with the terms of [Local Coverage Determination ID L36343](#), which sets forth specific coverage criteria for the Decipher Test. The relators claimed (among other things) that GenomeDx routinely billed for pre-surgery biopsies even though the LCD allowed coverage only for tissue obtained through surgery using the same CPT code to bill both types of specimens. While the treating physician rather than the laboratory performing the test is responsible for determining medical necessity, a laboratory must be mindful of the need to maintain clear documentation of medical necessity, especially when a national or local coverage determination applies.

The relators made a few other vague yet sensational allegations that presumably were not part of the conduct covered by the settlement because they were not mentioned in the press release. Everyone in the health care industry should be mindful that relators often make claims that the government chooses not to fully investigate or that the government cannot ultimately substantiate. When reviewing a relator’s complaint filed in a matter that ultimately settles, one should never assume that such claims are true. Moreover, a qui tam settlement rarely involves an admission of liability, even for the covered conduct.

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