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Genetic Testing Company Agrees to Pay $1.99 Million to Resolve Allegations that it Violated the False Claims Act By Billing for Tests Not Covered Under Local Coverage Determinations

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GenomeDx Biosciences Corp., which markets a genomic test (Decipher®) intended to assess the aggressiveness of prostate cancer, has agreed to pay $1.99 million to the U.S. Department of Justice to resolve allegations that it violated the False Claims Act (31 U.S.C. §§ 3729 *et seq*.)("FCA") by submitting claims to Medicare for tests conducted to evaluate treatment options for men after prostate surgery.

The government and a whistleblower alleged that between September 2015 and June 2017, GenomeDx knowingly submitted Medicare reimbursement claims for the Decipher® test that did not meet the six clinical prerequisites in the Local Coverage Determinations ("LCDs") published by each of the Medicare Administrative Contractors (MACs). LCDs are published by MACs when they make a determination that an item or service meets (or does not meet) the "reasonable and necessary" test in Section 1862(a)(1)(A) of the Social Security Act and under what circumstances. The prerequisites for a prostate cancer classifier assay to be deemed medically necessary include (1) evaluation for postoperative secondary therapy due to one or more risk factors for a recurrence within 60 months after a radical prostatectomy surgery, (2) no evidence of any distant metastasis, and (3) pathological stage T2 disease with a positive surgical margin or pathological stage T3 disease, or rising prostate-specific antigen levels after an initial test result of 0.2 ng/ml or less.

Therefore, for each claim, the government and the whistleblower alleged that GenomeDx had certified that the test was reasonable and necessary as defined in the LCD even though the clinical criteria or documentation requirements had not been met because the patients did not have risk factors necessitating the test.

The issue of medical necessity for diagnostic services continues to be a primary issue in many health care-related cases filed pursuant to the FCA. The federal courts have confirmed that a laboratory may rely on the ordering physician's determination of medical necessity because laboratories do not and cannot treat patients or make medical necessity determinations; however, laboratories may still be liable under the FCA if the laboratory knowingly presents claims for reimbursement that are not medically necessary.

Moreover, Medicare will still require documentation that demonstrates medical necessity to support payment for the test services. Thus, if adequate documentation is not provided, even when the ordering provider failed to maintain the appropriate diagnostic or other medical information for his or her patient, it is the laboratory that will suffer the consequences of the denial or recovery of reimbursement for the claim.

This settlement highlights the need for clinical laboratories, and all Medicare providers and suppliers, to determine if any national or local coverage policies apply to their services and the prerequisites prior to submission of claims, and to file those claims only where there is a good faith belief that any relevant prerequisites have been met. Jurisdiction of claims for laboratory services furnished by an independent laboratory normally lies with the MAC serving the area in which the laboratory test is performed. If there is a disagreement with the national or local coverage determination, there are procedures to either challenge the policy or to request that the policies be revised and updated.

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