FoundationOne CDx assay available in U.S.

written by CAP TODAY
April 16, 2018

April 17, 2018—Foundation Medicine announced that its FoundationOne CDx, an FDA-approved comprehensive genomic profiling assay for all solid tumors incorporating multiple companion diagnostics, is now available in the United States. FoundationOne CDx is a test for patients with advanced cancer and is offered as a nationally covered benefit across all solid tumors for Medicare and Medicare Advantage beneficiaries who meet eligibility requirements.

"Now that FoundationOne CDx is widely available in the U.S., oncologists can begin using this valuable test to help guide and simplify personalized treatment decisions for their patients," Vincent Miller, MD, chief medical officer at Foundation Medicine, said in a statement. "By integrating FoundationOne CDx early into routine clinical care, oncologists can create treatment efficiencies and expand access to biomarker-driven medicines for patients, with the potential to improve treatment outcomes."

FoundationOne CDx is a next-generation-sequencing-based IVD device for detection of substitutions, insertion and deletion alterations, and copy number alterations in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability and tumor mutational burden using DNA isolated from formalin-fixed, paraffin-embedded tumor tissue specimens. It is also FDA approved as a broad companion diagnostic for patients with certain types of non-small cell lung cancer, melanoma, colorectal cancer, ovarian cancer, or breast cancer to identify patients who may benefit from treatment with one of 17 on-label targeted therapies, 12 of which are approved as first-line therapy for their respective indications.

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