

CMS COVERS BREAKTHROUGH CANCER DIAGNOSTIC

The Centers for Medicare and Medicaid Services (CMS) granted broader coverage than it originally proposed for diagnostic laboratory tests using next generation sequencing, a breakthrough technology considered key to advancing personalized medicine that was approved following an unusual parallel review by CMS and the Food and Drug Administration (FDA). CMS will not make labs study the diagnostics in return for covering them. The Agency also expanded coverage to patients with relapsed, refractory or stage-three cancer and Medicare will pay for repeat testing when patients have new primary cancer diagnoses.

FDA approved FoundationOne CDx (F1CDx) in November, and CMS simultaneously proposed a national coverage determination. F1CDx is the first breakthrough-designated diagnostic to use a next-generation sequencing test. It's a companion diagnostic for 15 targeted therapies and detects genetic mutations in 324 genes and two genomic signatures in any solid tumor.

CMS originally proposed covering only FDA-approved companion in vitro diagnostics in patients with recurrent, metastatic, or advanced stage IV cancer. The final coverage policy widens that coverage to pay for testing in earlier stage cancer patients and patients with new cancer diagnoses.

Most tests that use next generation sequencing are developed by labs, and CMS originally proposed that tests without FDA approval would have been subject to Medicare's coverage with evidence development policy, which would have forced labs to individually get the tests approved or cleared by FDA. The American Clinical Laboratory Association said there is sufficient evidence already that the tests work and there are many other ways labs can show evidence of tests' scientific validity that don't involve FDA reviews. The final coverage policy states that tests that gain FDA approval or clearance as in vitro companion diagnostics automatically get full coverage. Coverage determinations for other diagnostics using next generation sequencing will be made by local Medicare Administrative Contractors. ■