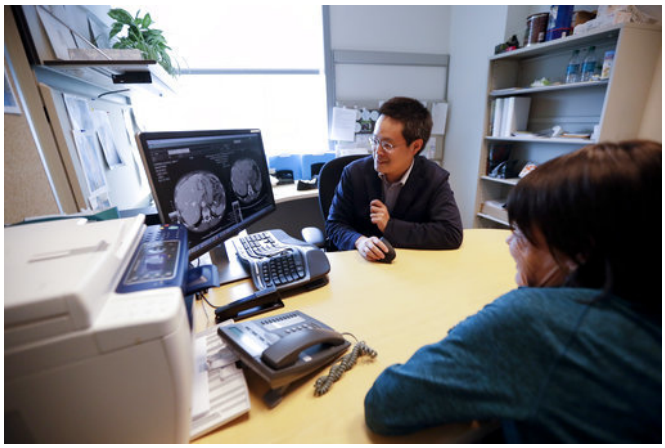
FDA approves first-of-a-kind test for cancer gene profiling

1 December 2017, by Marilynn Marchione



In this Aug. 15, 2017 file photo, patient Alison Cairnes, foreground, looks at images with her doctor Shumei Kato at the University of California San Diego in San Diego. Tumor profiling that sequenced Cairnes' cancer genes helped identify a treatment that proved effective for her gastric cancer. On Thursday, Nov. 30 the U.S. Food and Drug Administration approved one such test by Foundation Medicine. (AP Photo/Gregory Bull, File)

U.S. regulators have approved a first-of-a-kind test that looks for mutations in hundreds of cancer genes at once, giving a more complete picture of what's driving a patient's tumor and aiding efforts to match treatments to those flaws.

The U.S. Food and Drug Administration approved Foundation Medicine's test for patients with advanced or widely spread cancers, and the Centers for Medicare and Medicaid Services proposed covering it.

The dual decisions, announced late Thursday, will make tumor-gene profiling available to far more cancer patients than the few who get it now, and lead more insurers to cover it.

"It's essentially individualized, precision medicine," said Dr. Kate Goodrich, chief medical officer for the Medicare oversight agency.

Currently, patients may get tested for individual genes if a drug is available to target those mutations. It's a hit-and-miss approach that sometimes means multiple biopsies and wasted time. In lung cancer alone, for example, about half a dozen genes can be checked with individual tests to see if a particular drug is a good match.

The new FoundationOne CDx test can be used for any solid tumor such as prostate, breast or colon cancer, and surveys 324 genes plus other features that can help predict success with treatments that enlist the immune system.

"Instead of one or two, you have many" tests at once from a single tissue sample, said the FDA's Dr. Jeffrey Shuren. The tests give better and more information to guide treatment and can help more patients find and enroll in studies of novel therapies, he said.

"This will be a sea change" for patients, said Dr. Richard Schilsky, chief medical officer of the American Society of Clinical Oncology, the association of doctors who treat the disease.

"On balance I think this is good," but there is a risk that spotting a mutation will lead doctors and patients to try treatments that haven't been proven to work in that situation and promote more off-label use of expensive drugs, he said.

A better outcome in those situations is to guide people into studies testing drugs that target those genes, Schilsky said.

Foundation Medicine, based in Cambridge, Massachusetts, and others have sold tumor profiling tests for several years under more lax rules governing lab-developed tests. But insurers have balked at paying for the tests, which cost

around $6,000.

Now, the FDA's approval gives assurance of quality, Shuren said, and the government's proposed coverage for Medicare and other public insurance programs means private insurers will more likely follow.

Public comments on the coverage proposal will be taken for 30 days. A final decision is expected early next year followed by setting a price for reimbursement.

Coverage is proposed for patients with recurrent, widely spread or advanced cancers, in people who have decided with their doctors to seek further treatment and who have not previously had a gene sequencing test.

"A lot of these folks have run out of treatment options," but the tests may point to something new that might help, Goodrich said.

The impact is expected to be greatest on lung cancer, since so many of those tumors are found at an advanced stage and multiple gene-targeting drugs are available to treat it.

Evidence isn't strong enough to warrant using these gene profiling tests for earlier stages of cancer. Patients get standard, guideline-based care in those cases.

In mid-November, the FDA also approved a gene-profiling test developed by Memorial Sloan Kettering Cancer Center, but it's used almost exclusively on patients at that cancer center and is not envisioned to be a widely available commercial test.

The federal decisions will make gene sequencing a more routine component of cancer care, "just like we normally look with a microscope" to classify the stage of a patient's disease, said Dr. David Klimstra, pathology chief at the cancer center.

Another leader in this field, Caris Life Sciences, says it also intends to pursue FDA approval for its widely used tumor profiling test, sold now through lab certifications. It's also working on a newer tool to profile tumor genes from a blood sample. Many companies already sell these so-called liquid biopsy tests, though none are FDA-approved yet.