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Personalized Medicine

Will Medicare Genetic Test Coverage Get Labs to Seek FDA Signoff?

BNA Snapshot

- New policy only covers costs of gene sequencing tests approved by the FDA
- Laboratory-developed tests currently not regulated by FDA

By Greg Langlois

Medicare's decision to cover a limited number of personalized medicine tests for cancer patients could nudge laboratory testing companies to ask the FDA to approve them—something the FDA sought for several years.

An announcement by Medicare to cover genetic tests using next-generation sequencing (NGS) technology—only if they are FDA-approved companion diagnostics—could spur laboratory diagnostic testing companies to obtain the FDA's blessing.

Clinical labs, already regulated by the Centers for Medicare and Medicaid Services (CMS), would prefer to avoid FDA oversight on top of that—what they've said would be double regulation. But the promise of Medicare coverage for NGS tests might be too tempting to pass up, even it means their tests have to be treated as medical devices under FDA regulations.

“[T]hey might go ahead and get FDA approval or clearance so that they could be eligible for reimbursement,” Lee & Hayes PLLC partner Carol Pratt told Bloomberg Law in an interview. “[N]ow it's advantageous for them from a business model to do that because they will open the door to reimbursement.”

No FDA Approval, No Coverage

Next generation sequencing is a laboratory method that enables rapid sequencing of large sections of DNA derived from a patient's specimen (blood or saliva). The increased efficiency of NGS, combined with reductions in cost, has made it feasible for laboratories to deliver large quantities of genetic information to physicians. In the case of cancer, NGS has been used to sequence both tumor DNA and the patient's own (germline) DNA, in order to help physicians develop more precise treatment plans for their patients.

With the Centers for Medicare & Medicaid Services (CMS) saying the federal insurance program will definitely cover only the NGS tests that are FDA-approved companion diagnostics, laboratory-developed test providers may seek FDA approval anyway in order to secure coverage for their offerings. A companion diagnostic provides information that is essential for the safe and effective use of a corresponding drug or biological product.

A Foundation Medicine Inc. NGS test, approved by the FDA in November, is the only NGS companion diagnostic to qualify under the new Medicare coverage policy. The test, called FoundationOne CDx, will hit the market by the end of March and will be the only FDA-approved broad assay for all solid tumors, company chief executive officer Troy Cox said in a statement. Foundation Medicine is based in Cambridge, Mass.

The FDA has long sought to regulate laboratory-developed tests—those designed, manufactured, and used within a single laboratory—as medical devices, but the industry has strongly pushed back. The FDA has said the increasing complexity of diagnostic tests warranted more oversight, and it has sought to have test developers demonstrate results are valid and useful to patients.

“[T]here's this big debate about whether or not the FDA really has the legal authority to regulate those as medical devices because [providers] don't sell the device—they sell the results,” said Pratt, an FDA regulatory attorney in Portland, Ore. The Medicare NGS annoucement “is like another chapter in the FDA's ongoing saga about trying to regulate laboratory-developed tests,” she said.

The American Clinical Laboratory Association has consistently maintained that laboratory-developed tests are not medical devices and cannot be regulated as such. The labs group represents Quest Diagnostics Inc., Laboratory Corporation of America Holdings, and other companies, including Cancer Genetics and Genomic Health Inc., which each submitted comments on the draft coverage decision CMS issued in November.

ACLA said in a statement it is evaluating CMS's move after the agency “made significant changes from the draft [coverage decision] as a result of the concerns expressed by many stakeholders.”

Incentive for FDA Approval?

Laboratory-developed tests, although currently exempt from FDA regulation, are subject to the Clinical Laboratory Improvement Amendments, through which CMS regulates all laboratory testing performed on humans in the U.S., except research testing. CLIA standards are designed ensure quality laboratory testing. All clinical laboratories must be CLIA-certified to receive Medicare or Medicaid payments.

“I think those companies that already have established businesses will most likely continue to market their products under the LDT exemption,” Buchanan Ingersoll & Rooney PC shareholder William Garvin told Bloomberg Law in an email. “But I think for new companies that are debating whether to develop the product as an LDT or pre-market approved medical device, this decision could help them choose the [medical device approval] route.”

But the FDA-approval requirement may put some laboratories off, Epstein Becker Green health-care and life sciences member Gail Javitt told Bloomberg Law in an interview.

“This is an industry that has never been subject to FDA oversight, and there's a lot more that goes along with going through FDA than just the approval,” Javitt said. “You are effectively becoming an FDA regulated device manufacturer. And so for some, it will just not be a viable strategy.”

Among other things, not being treated as a medical device would allow laboratory-diagnostic test companies to modify it “anytime that they want, without having to go back to the FDA,” Pratt said.

“If you change it in a subsantial way, you're required to to back to the FDA and say, ‘Hey, we changed it,’” she said. “And that's always a gray area—how much change requires going back to the FDA?”

Concerns About Validity, Efficacy

CMS’ final national coverage decision says Medicare will cover FDA-approved NGS companion diagnostic laboratory tests nationwide when ordered by a physician and the patient has advanced cancer (stage III or IV), has not previously been tested using the same NGS test for that cancer diagnosis, and has decided to seek further cancer treatment, such as chemotherapy.

CMS may have included the FDA-approval requirement out of a concern that without it, CMS would “be forced to pay for some tests that either were not accurate, did not have enough sensitivity or specificity to be useful, or did not add a clinical meaningful benefit to patients,” Garvin said.

“By having FDA act as a gatekeeper to which tests will get covered, CMS is encouraging development into the area while ensuring that only quality products receive reimbursement,” he said. Garvin's FDA regulatory practice includes medical devices.

But NGS tests operating under CMS's CLIA standards already are in clinical use, and are required under CLIA to show analytic validity, Javitt said.

“[T]he majority of genetic tests are LDTs, and that's true in cancer and beyond cancer,” she said. “I do think that there's a bit of a regulatory disconnect between how FDA has been approaching these tests and how clinicians have started to use them, and CMS’ rather narrow approach.”

Although NGS tests without FDA approval will not be covered under CMS’ nationwide policy, individual Medicare

administrative contractors (MACs) still have discretion to cover unapproved tests.

“There was some level of relief that CMS left open to the individual MACs whether to cover, but that is a case-by-case basis,” Javitt said. “[I]t could be a very fragmented environment for test coverage.”

To contact the reporter on this story: Greg Langlois in Washington at glanglois@bloomberglaw.com

To contact the editor responsible for this story: Randy Kubetin at rkubetin@bloomberglaw.com

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