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Better Coverage For Cancer Screening Tests On Horizon

by Elizabeth Orr

Multi-cancer diagnostics can help get oncology patients the treatment they need more quickly, but lack of reimbursement has kept such tests out of reach for many patients. Bills providing coverage have passed or are under consideration in more than half of the states and have been introduced in both houses of US Congress.

Cancer biomarker tests are critical to determining the best course of treatment for many oncology patients, but access to them has been limited by a lack of insurance coverage. Legislative efforts to address the issue are underway at the US state and national level, speakers said at the NextGen Dx Summit in Washington, DC.

Multi-cancer early detection (MCED) tests are diagnostics that can identify biomarkers for multiple types of cancer, many of which are not detected by broadly available screening tests like colonoscopies or mammograms. They are rarely covered by insurance, meaning patients must pay for the tests out of pocket.

Hilary Gee Goeckner, who directs state and local campaigns for the American Cancer Society Cancer Action Network (ACS CAN), said lack of insurance coverage poses a barrier to access to appropriate testing.

"Sixty-six percent of oncology providers reported that insurance coverage of needed testing is a moderate or significant patient need," she said, noting that access to testing is especially limited in rural and low-income communities. "Without coverage, patients will continue to be left behind."

For example, a lung cancer patient whose insurance does not cover all recommended genetic tests might only be screened for the most common variants, Goeckner said. If the patient has a

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less common mutation that is not included in those tests, that could delay proper treatment for months. By contrast, a patient whose insurance covered comprehensive testing upfront would be able to start targeted treatment right away, avoiding months of disease progression and ineffective treatment with potentially severe side effects.

20 States Have Some Biomarker Testing Coverage

ACS CAN is working with other advocacy and medical organizations to pass legislation requiring state-regulated insurance plans to cover biomarker testing. The policies specifically apply to MCEDs that are supported by evidence such as Food and Drug Administration approval or clearance, Medicare coverage determinations, or nationally recognized clinical guidelines.

Proposed legislation would apply equally across all types and stages of cancer and would cover biomarker testing for diagnosis, treatment or disease management or monitoring, Goeckner said.

Bills covering at least some biomarker testing have passed in 20 states and are under consideration in nine more (see map below).

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Some of the bills are still limited, Goeckner noted. The Arkansas and Louisiana laws apply only to state-regulated private plans, while the Connecticut law applies only to Medicaid. In Florida, the law applies to Medicaid as well as the state employee health plan.

Regardless, advocates believe success is on the horizon.

"I don't like trying to look too far into the future, but I think it's likely that in the next three to five years, a large majority of states will have some sort of biomarker coverage law in place," said Christian Johnson, director of government affairs at Myriad Genetics.

Federal Bill Would Create MCED Medicare Category

At the national level, legislation that would add MCED coverage to Medicare is under consideration in both the Senate (<u>S. 2085</u>) and the House of Representatives (<u>H.R. 2407</u>). Right now, Medicare cannot cover the screening tests because they do not fit into an established benefit category. The proposed legislation would fill that gap by creating a benefit category for MCED tests. CMS could then initiate the National Coverage Determination process for any multicancer tests cleared by the FDA.

A national program would allow Medicare beneficiaries to access the tests and create needed

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uniformity across state policies, Johnson noted. A <u>letter</u> in support of the legislation sponsored by the Prevent Cancer Foundation has drawn support from hundreds of medical and patient advocacy groups.

Johnson encouraged test manufacturers to lobby for the bills' passage by mobilizing and partnering with stakeholders such as pharmacy groups and patient groups, working with key government agencies such as Medicaid administrators, and finding allies in House and Senate leadership if possible.

"There is a tremendous opportunity under biomarker laws, and the more work that we do as an industry to come together advocating for this, I think we can evolve and hopefully succeed," he said.