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Labs, Advocacy Groups Push Back on Medicare Policy Shift on NGS Testing for Hereditary Cancer Risk

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NEW YORK (GenomeWeb) – Labs and advocacy groups are alarmed by recent revisions to Medicare coverage policy that they say will limit reimbursement for next-generation sequencing panels for assessing hereditary cancer risk, as well as patients' access to these tests.

Earlier this month, Medicare contractor Palmetto revised its local coverage determination (LCD) for BRCA1 and BRCA2 testing, and indicated that it will not cover NGS-based multi-gene panels to determine whether stage I or stage II cancer patients have an inherited predisposition for breast and ovarian cancer.

Medicare Administrative Contractors (MACs) have for several years been covering germline testing of hereditary cancer risk genes, BRCA1 and BRCA2, for patients who have cancer or previously had cancer, but didn't restrict coverage based on whether they had early or late-stage disease. Palmetto's policy revision, if implemented, would be a major shift from these prior LCDs.

"It would eliminate the ability of the MACs to cover NGS germline testing for anyone other than those with advanced, late-stage cancers," said Rob Guigley, VP of market access at Konica Minolta subsidiary Ambry Genetics, which provides this type of testing.

The LCD, as currently worded, suggests that Medicare wouldn't restrict coverage for stage I/II patients when testing is done by other technologies, such as Sanger sequencing or PCR, but industry players said this is out of step with current practice, which has shifted to NGS-based assessments of hereditary cancer risk. "Yes, you could do BRCA testing with Sanger sequencing, but nobody does it anymore," said Lisa Schlager, VP of community affairs and public policy at the patient advocacy organization Facing Our Risk of Cancer Empowered.

Palmetto revised the LCD in order to align it with the Centers for Medicare & Medicaid Services' national coverage determination for NGS cancer profiling tests. That national policy, entitled "Next-Generation Sequencing for Medicare Beneficiaries With Advanced Cancer," and finalized March 16, 2018, extended coverage for NGS testing for patients with recurrent, relapsed, refractory, metastatic, or advanced stage III or IV disease who are seeking treatment.

In the lab community, Palmetto's LCD revision has sparked "a huge amount of confusion, because the final NCD was widely interpreted to be only relevant for evaluation of [somatic variants associated with] cancer," said Guigley. "It appears the way CMS structured the language in the NCD may implicate all NGS tests regardless of what you're analyzing, be it somatic or germline mutations."

NGS tests that gauge somatic variants are used to identify mutations driving a patient's tumor and drugs that target them. Covering these tests for advanced cancer patients makes sense since most precision oncology drugs are indicated for this setting. In contrast, testing for germline variants that are inherited by every cell in the body can reveal whether someone is at risk for a hereditary disease.

Applying an NCD intended for NGS tumor profiling tests to germline testing "isn't logical," said Lee Bendekgey, chief operating officer of Invitae, another genetic testing lab with a growing presence in the NGS cancer testing space. He believes that the coverage revision stems from a misunderstanding at CMS about when germline and somatic NGS testing is done. "They've created a bit of a mess," Bendekgey said.

The revised language in the LCD "really shocked us," added Schlager, who estimated that the policy shift could hinder a lot of Medicare eligible cancer patients from getting germline testing, since approximately 60 percent of patients have stage I or II disease.

The revision also runs counter to the primary goal of testing for cancer risk, which is to prevent cancer. Women with mutations in BRCA1 or BRCA2, for example, have a heightened risk for breast and ovarian cancer, and if this information is known early enough, they can reduce their risk via preventive surgery. Some experts in the field have pointed out that waiting to test people until they have cancer is too late and have called for the implementation of a population screening approach for BRCA1/2 mutations in unaffected individuals.

Ovarian cancer, in particular, is a disease often caught when a patient's disease is in advanced stages and her chance of survival is greatly reduced. "If a woman with breast cancer finds out she has a mutation, then hopefully, we can prevent that ovarian cancer later," Schlager said. "We try to look at the bigger picture but that's not Medicare's focus."

In her view, the LCD revision would not only cut existing benefits for Medicare patients but would also be a step back for precision medicine. In recent years, companies like Invitae, Color Genomics, and others have lowered the price of NGS panel tests for hereditary cancer risk and other tests to a few hundred dollars, in part because there is mounting data showing that payors' coverage criteria don't account for a significant proportion of the mutation-carrying, at-risk population.

Invitae studied almost 4,200 Medicare patients and showed that 10.5 percent of those that met Medicare coverage criteria for BRCA1/2 testing had a pathogenic or likely pathogenic variant, while 9 percent of those that didn't meet coverage criteria also carried such variants. "What this shows is that they are underserving their beneficiaries," Bendekgey said. "There are plenty of Medicare patients who aren't being tested, who should be tested."

Gaps in care, once identified, can become opportunities to improve prevention and further personalize care, but labs and patient advocates fear that if the latest coverage revision is implemented, it would only widen inequitable access to lifesaving interventions. "Our goal is to move forward and make progress toward precision medicine," Schlager said. "This goes in the completely opposite direction."

"Significant policy overreach"

The policy shift, if allowed to stand, would not only impact patient access to tests but also lab revenues. "If this is relevant for germline testing, it would have a major impact on coverage because almost all labs use NGS as their core technology," Guigley said, adding that Ambry does perform orthogonal analysis using non-NGS platforms.

Recognizing this, the American Clinical Laboratory Association has sprung into action on behalf of its lab industry members and has been having discussions with CMS.

"Our goal is to ensure Medicare patients have access to NGS and other cutting-edge technologies that make a major difference in the early diagnosis and treatment of cancer and other diseases," said ACLA President Julie Khani. "A number of questions have been raised during implementation of the NGS NCD, and we are actively seeking clarification from CMS to ensure Medicare beneficiaries maintain access to the tests they need."

The Association for Molecular Pathology also expressed concern with CMS' "overly broad interpretation" of the NCD. Mary Williams, AMP's executive director, characterized CMS' decision to extend the NCD coverage criteria to germline testing as "a significant policy overreach."

While Palmetto is the first MAC to revise its local coverage determination in this way, those knowledgeable of the issue said that CMS has instructed all MACs to make these changes. "It is our understanding that despite the NCD being requested for a somatic-based test, CMS has also been instructing MACs to apply the terms of the NCD to germline NGS testing," Williams said. "CMS should not be creating additional barriers to Medicare beneficiaries' access to clinically appropriate NGS-based testing. … We strongly urge CMS to limit its current interpretation of the NCD to somatic tumor testing."

CMS did not reply to emailed questions ahead of publication about why it believes the NCD criteria applies to NGS germline testing for breast and ovarian cancer risk. But close readers of the NCD said the history of the national coverage policy, as well as the agency's own communications in the final NCD, don't align with CMS's current take.

The NCD was triggered by Foundation Medicine's bid to simultaneously garner regulatory approval and national coverage for FoundationOne CDx, a test that gauges somatic variants in 324 genes from tumor tissue samples. After CMS issued the draft NCD in 2017, some industry observers noted that the language in the preliminary policy could be

interpreted in a way that narrows coverage for germline NGS testing to late-stage cancer patients. The final NCD alleviated those concerns because CMS wrote that "this decision is not applicable to all diagnostic laboratory tests using NGS, but rather to a unique diagnostic laboratory test that uses NGS for patients with cancer to manage the patient's cancer by identifying either targeted therapies with known efficacy or in some cases, eligibility for a cancer clinical trial."

Reimbursement expert Bruce Quinn has noted that the most common sense interpretation of the NCD would be that it addresses the kind of testing it was initiated for — NGS tumor profiling — and that it does not comprise other types of NGS applications that CMS doesn't bother to bring up in coverage criteria. "It's hard to imagine that a sweeping exclusionary effect of the NCD to topics never named or addressed would stand up to NCD judicial review on the grounds of being capricious," Quinn wrote in an April 2018 white paper on the topic.

Better ways to save

For the time being, neither CMS nor Palmetto has denied any claims based on this policy revision. "There is still confusion about this policy and about billing," said Guigley. "We haven't seen an impact from this yet."

It's also unclear if CMS plans for this policy to take effect from the time the LCD was revised, or if the clock would start with the release of the final NCD in March 2018. Either way, if the policy is enforced, it would certainly be felt by labs like Myriad Genetics, Ambry, and Invitae who operate NGS-based hereditary breast and ovarian cancer risk testing services and do significant business in the space. Myriad, the leading provider of hereditary breast and ovarian cancer testing, declined to comment for this story.

Palmetto's LCD revision is in line with payors' stepped-up efforts to contain spending in recent years as genetic testing utilization has increased. However, Invitae's Bendekgey suggested there are other ways for CMS to save money than by restricting NGS test access to patients who would benefit from learning their hereditary cancer risk.

Medicare spending on molecular diagnostics increased from $256 million in 2013 to $644 million in 2017, and during this time spending on genetic tests for hereditary cancer risk also increased. For example, CMS spent $57 million on BRCA testing in 2013, but by 2017, the bill for such tests grew to $75 million.

One way the agency has tried to rein in spending is by limiting labs' ability to bill stacked CPT codes, which describe different components of the testing process. But CMS's enforcement of laboratory billing practices has been inconsistent.

For example, there are a variety of CPT codes that labs can use to bill for hereditary breast and ovarian cancer risk testing, and some labs have been billing the codes or combination of codes that will bring the biggest payment. As a result, one lab may get reimbursed significantly more than another lab for providing the same type of test.

CMS and Medicare contractors have instructed labs performing NGS panel testing for hereditary breast and ovarian cancer risk to bill CPT codes 81432 and 81433, which amounts to around $1,300. Invitae bills using these codes, but Bendekgey noted that some competing labs instead bill CPT code 81162, which describes BRCA1/2 sequencing and duplication/deletion analysis and is currently priced at around $2,000.

Bendekgey said Invitae's analysis showed that Medicare could have saved tens of millions of dollars if it had just enforced use of CPT codes 81432 and 81433, and turned off 81162. "We would hope that by reducing overspending because of the coding games some labs play, that [CMS] could free up dollars that then could be used to provide better care for patients who actually need it," he said.

In a recent report, the US Government Accountability Office also advised CMS to save money by paying bundled rates for panel tests. If Medicare continued unbundled payments for panel tests, its expenditures could increase by $10.3 billion from 2018 through 2020, the GAO estimated.

Statutory change

CMS's move to deny coverage for NGS-based hereditary cancer risk testing, according to FORCE's Schlager, is reflective of the fact that the agency isn't typically focused on prevention. The advocacy organization has heard from patients who at one point had breast cancer and tested positive for BRCA1/2 mutations, but once they became

eligible for Medicare couldn't get coverage for the mastectomies and oophorectomies that could prevent other cancers.

Medicare beneficiaries who are family members of individuals with cancer risk mutations often want to be tested as well. FORCE has heard from mutation carriers whose parents have Medicare, but have had to pay out of pocket for testing because they haven't had cancer as stipulated by coverage criteria. "There's a chance here to prevent people from getting late-stage cancer or prevent cancer altogether," Schlager said. "Why wouldn't we do that when we could, especially when the cost of testing has gone down so much?"

To address these barriers, FORCE is working on writing legislation to change the Medicare statute to allow BRCA1/2 testing for unaffected carriers who have a known mutation in the family or have sufficient family history to warrant testing. The bill under development would also ensure that Medicare beneficiaries who find out they harbor mutations can access additional screenings and preventive surgeries.

Schlager acknowledged it is a challenging time to make headway on any legislation in Congress. But at a minimum, FORCE plans to partner with others in the testing community and influential cancer organizations, and shore up support among legislators to try to convince CMS to reverse its policy on NGS testing for hereditary breast and ovarian cancer risk.

When stakeholders from the lab community had a call with CMS to discuss this issue, the government payor seemed open to considering an NCD revision request, a six-to-nine-month process. "But if the policy is effective as of now, this could impact millions of Americans' access to this testing that has been the standard of care for years," Ambry's Guigley said.

"Once the large and vocal cancer patient advocacy groups get involved, this [policy] will be hard to sustain," predicted Bendekgey.

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