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Evolving Payer Coverage Policies on Genomic Sequencing Tests:

Beginning of the End or End of the Beginning?

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Reimbursement has been cited as a key barrier to the adoption of precision medicine into clinical care.[1] This issue has recently attracted attention with the March 2018 Centers for Medicare & Medicaid Services (CMS) national coverage determination on next-generation sequencing tests for patients with advanced cancer.[2]

This policy represents a step forward by addressing the vexing issue of coverage for these complex tests. Private and public coverage for next-generation sequencing tests for patients with cancer and those with other conditions is currently limited and variable[3] and the new policy offers a roadmap for coverage. The policy provides coverage for companion diagnostics that have approved indications by the US Food and Drug Administration for patients with advanced cancer. The final policy was significantly different from the draft issuance, which generated controversy as evidenced by 315 comments submitted to the CMS, publication of several opinion articles and editorials, and intense industry lobbying.

In the draft issuance, there were 2 coverage pathways: (1) approved tests by the FDA meeting all criteria are covered and (2) other tests could be covered via Medicare's coverage with evidence development program if laboratories collected the required data. A particularly notable change is that the final policy removed the second pathway and replaced it with the option of seeking a local coverage determination through regional Medicare administrative contractors, which means that these types of Medicare contractors will have discretion on which tests to cover. The final policy also broadened coverage to a wider group of patients with cancer (ie, recurrent, relapsed, refractory, metastatic, or advanced stage III or IV).

However, issuance of the new policy does not imply that coverage issues are now resolved. It is important to address the broader policy implications of this new coverage approach.

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Although this policy covers only a specific type of testing for a specific patient group, it is possible that the general coverage approach used may be applied to other tests and conditions in the future. For example, next-generation sequencing tests are available for early-stage cancer, hereditary cancer, developmental delays in children, carrier and prenatal screening, drug metabolism testing, and cardiovascular and metabolic diseases.

Commentators have addressed the implications of the CMS policy for patients, clinicians, health care organizations, and industry, but a health policy agenda needs to be developed to address the broader implications and to facilitate the development of the evidence needed for appropriate, efficient, and equitable policies and implementation. The following questions should be considered.

Will the New Policy Provide Appropriate and Equitable Access to Testing?

The CMS policy will undoubtedly increase access for some patients. However, it is unclear if access will increase for patients who are tested using next-generation sequencing tests that are not immediately covered by the new policy or who are covered by payers other than Medicare.

One key question is whether Medicare administrative contractors will cover next-generation sequencing tests when patients and their clinicians choose 1 of the many available tests that are not covered by the new policy. The general public typically assumes that Medicare policies are national and that every enrollee has the same coverage but this is a mistaken assumption. Some Medicare coverage policies are made at the local level and these policies create inconsistency in Medicare coverage.[4] It is also not widely understood that most genomic tests in the United States are developed and performed at specific laboratories (laboratory-developed tests); these tests receive quality approvals via the Clinical Laboratory Improvements Amendments but are not approved by the FDA. Thus, many Medicare patients may not have immediate access to covered next-generation sequencing tests because their clinician orders a specific laboratory-developed test that is not approved by the FDA and covered by their local Medicare administrative contractor.

Another important question is whether private payers will change their coverage policies (beyond their Medicare Advantage policies) to match the CMS policy, given that many private-payer coverage policies currently have limited coverage of next-generation sequencing tests.[3] Many individuals who are eligible for Medicare are still employed and have private insurance. Private payers do not necessarily follow Medicare's lead for their commercial policies and may not change their policies to correspond with the CMS policy because many aspects of the policy are inconsistent with their current policies and their approaches to coverage.[5] In particular, many payers require that all genes in a panel have evidence of clinical utility in order for the panel to be covered, and they do not rely only on FDA approvals for determining medical necessity.

A neglected question is whether Medicaid enrollees and uninsured patients will have access to next-generation sequencing tests. Medicaid policies vary widely by state. Although there

has not been a published analysis of access to these tests for these patients, it is likely that access may be limited and variable especially in today's health care environment.

Some experts have asserted that all payers should apply the same coverage framework, in the same manner, and thus have consistent policies. However, payers behave quite differently from one another. Every payer has to consider its own enrollees, available resources, constraints, and mandates. Thus it should not be surprising when payers do not follow the CMS policy. The CMS policy did not emerge de novo, but rather reflects an evolution of coverage frameworks that will not end with this decision. Private and Medicaid plans have and will continue to develop their own innovative approaches to coverage policies. Regardless, all policies should be transparent, driven by evidence, and applied appropriately and equitably.

Will the New Policy Be an Efficient Use of Resources?

Despite the goal to reduce Medicare expenditures, the mandate of the CMS prohibits consideration of costs in coverage decisions and thus cost-benefit trade-offs for the tests covered in the policy and for the policy as a whole were not considered. A recent review found that only 6 cost-effectiveness analyses of next-generation sequencing testing in patients with cancer have been published, and 50% of these studies found that testing was not cost effective.[6]

The next-generation sequencing tests and implementation of the CMS policy should be evaluated for their benefits and costs to address the question of what are the most efficient approaches to testing and to policy implementation. The need to examine the trade-offs between benefits and costs is important. Resources are limited and allocation decisions must be made.

Will the New Policy Improve Patient and Societal Outcomes?

The CMS reviewed numerous studies on the clinical benefits of next-generation sequencing tests and found the evidence sufficient to support their specific policy. However, the benefits of widespread next-generation sequencing testing for patients with cancer continues to be debated.[7,8] Some patients will benefit from testing but others will not, and there is no consensus as to whether the overall benefits outweigh the potential disadvantages. In addition to the benefits to individual patients, policies should consider societal outcomes and be designed to facilitate the best possible outcomes for both patients and society. The CMS policy may stimulate innovation, but the removal of the requirement for evidence development may adversely affect creation of the robust evidence base that is needed. Answering these questions will require an assessment of the broader effect of the policy itself, not just the benefits of testing for specific patients.

In conclusion, new approaches to coverage for next-generation sequencing tests are needed, and the CMS policy represents a step forward. However, it is only the beginning of what will be an ongoing discussion as the science evolves. The United States must now examine the broader questions and implications to ensure that all individuals receive appropriate,

efficient, and equitable care and that the ultimate result is improved health and societal outcomes.

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