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Insurance coverage for genomic tests.

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adopting the structured process we propose.

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Insurance coverage for genomic tests

On 16 March, the Centers for Medicare and Medicaid Services (CMS) announced that Medicare will cover Food and Drug Administration (FDA)–approved or cleared genomic tests that encompass broad gene panels for advanced cancer patients (*1*). The final policy does not include the initial draft's proposed "coverage with evidence development" (CED)—i.e., coverage of tests run as part of clinical trials and registries—which some had argued should be applied to develop a stronger evidence base for these tests (*2*). Instead, tests not already approved in the national coverage determination can be reviewed for coverage by local Medicare Administrative Contractors (MACs). The new policy reflects a substantial shift in determining how genomic tests are evaluated for coverage, which provides a needed "roadmap" for coverage. However, to develop effective and efficient policies, stakeholders should support further research to address how the new policy will affect ongoing cancer research as well as the access to and affordability of next-generation sequencing testing for cancer patients.

The new policy has the potential to increase access to testing, but it may remain out of reach for many patients. Private payers may not follow the CMS policy for covered tests, as there are myriad reasons that payers have limited their coverage for broad genomic tests

(*3*), and private payers often do not use Medicare policies as precedents (*4*). The tests that remain uncovered by CMS may not be covered by local MACs either (*5*). The numerous laboratories that offer their own tests that do not currently meet the coverage requirements in the new policy may have trouble finding the trial participants and funding they need to obtain the evidence required. Although CMS's policy may spur these laboratories to develop evidence even without a CED requirement, this process may take several years, and its outcome is uncertain (*4*). The CMS policy is binding only on Medicare; it is uncertain whether states will cover these tests for Medicaid patients (*6*).

Likewise, the policy may increase affordability and equity for these tests, but with caveats. Benefit-cost tradeoffs were not examined as they are outside the scope of CMS. CMS is caught in an ongoing dilemma: Coverage policies are determined irrespective of cost, yet there is a constant drumbeat of calls to reduce Medicare expenditures (*7*). Lastly, it will be important to understand the implications of the new policy for genomic tests for patients with other types of cancer and with other conditions, which face similar challenges to coverage (*8*).

Given today's challenging health policy environment, CMS should work with stakeholders, including other federal agencies, to carefully evaluate the benefits and risks of this novel coverage approach and to consider what additional policy mechanisms will be needed to ensure that the necessary evidence is generated. We must address the substantial uncertainty about the impact of coverage policies on the health outcomes of Medicare beneficiaries.

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