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# CMS finalizes National Coverage Determination for Next Generation Sequencing Tests for advanced cancer

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On Friday, March 16, Centers for Medicare & Medicaid Services (CMS) finalized its National Coverage Determination (NCD) for Next Generation Sequencing (NGS) tests for Medicare beneficiaries with advanced cancer. In the draft NCD issued in November 2017, CMS had proposed national coverage of NGS tests only if they had Food and Drug Administration (FDA) approval as companion diagnostics, and would have covered other tests only if they met stringent requirements for Coverage with Evidence Development (CED). In the final NCD, however, CMS backed away from its CED proposal, and will allow Medicare Administrative Contractors (MACs) to continue developing Local Coverage Determinations (LCDs) for NGS tests that aren't FDA cleared or approved as companion diagnostics. In addition, CMS expanded its national coverage to certain tests that are FDA cleared (via a 510(k)) as well as those approved (via a premarket approval); testing for patients with Stage III, rather than just Stage IV, cancer; and repeat testing with the same NGS test if a new primary cancer is diagnosed.

This NCD was initiated in response to a request from Foundation Medicine, whose FoundationOne CDx™ (F1CDx) companion diagnostic had been accepted into FDA and CMS's "Parallel Review" process. When FDA issued its approval for the F1CDx, CMS opted to develop an NCD that applied more broadly to all NGS tests for advanced cancer. While there was broad support for CMS's decision to cover FDA approved companion diagnostics, the agency got significant negative comments on its proposal to require all other NGS tests to meet onerous CED criteria, and establish a policy of non-coverage for any tests not meeting these requirements. This proposed NCD called into question the future coverage of many NGS tests that currently are covered by Medicare under LCDs, and many others in development. CMS received over 300 comments on its proposal, most of which either opposed the NCD or supported it but requested modifications that would better protect beneficiary access to NGS tests that aren't FDA cleared or approved and are being offered as laboratory developed tests. Many commenters particularly expressed concern about the time and expense that would be required to meet CMS's proposed CED requirements.

**Under the final NCD, NGS tests will be covered as follows:**

- Patient criteria:
  - Medicare beneficiaries with either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer
  - Either have not been previously tested with the same NGS test for the same primary diagnosis, or repeat testing with the same test only if a new primary cancer diagnosis has been made by their treating physician
  - The patient has decided to seek further cancer treatment (e.g., chemotherapy)
- For Medicare beneficiaries meeting the above criteria, CMS **will cover on a national basis**:
  - NGS tests that are FDA cleared or approved as companion diagnostics;
  - The test has an FDA cleared or approved indication for use in that patient's cancer; and
  - The results are provided to the treating physician for management of the patient using a report template to specify treatment options.

**For all other NGS tests** offered to beneficiaries meeting the same patient criteria, **Medicare Administrative Contractors (MACs) may determine coverage** when the test is performed in a CLIA certified lab and ordered by a treating physician.

By reversing its proposal to require CED for most NGS tests, and allowing Medicare contractors to continue covering these tests under LCDs, CMS has preserved access to currently covered tests and maintained a less onerous pathway to coverage for additional NGS tests. CMS did say in the final NCD that they "continue to believe that FDA approval or clearance demonstrates analytical and clinical validity", and encouraged the continued development and publication of studies on the endpoints of overall survival, progression-free survival, objective response, and patient-reported outcomes relevant to the quality of life for Medicare beneficiaries. It remains to be seen whether MACs will alter their LCD criteria for coverage of NGS tests in response to the NCD.

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