On March 16, 2018, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) for Next Generation Sequencing (NGS) as a diagnostic laboratory test for patients with certain advanced stages of cancer. The NCD process was initiated by Foundation Medicine, Inc.’s request for Medicare coverage for its FoundationOne CDx test, the first FDA companion diagnostic that can detect genetic mutations in solid tumors. The NCD provides for Medicare coverage of NGS tests that have been FDA-approved or cleared as a companion diagnostic for patients with certain stage III or IV cancers. In addition, the NCD delegates authority to Medicare Administrative Contractors (MACs) to determine local coverage for tests that do not meet the NCD’s FDA criteria.

Holding a key role in the area of precision medicine, NGS is the second technology, and also the second category of vitro laboratory tests, to have successfully completed the FDA-CMS Parallel Review Program. The first in vitro diagnostic to be approved and covered under the Parallel Review Program was Cologuard®, a multi-target sDNA colorectal cancer screening test for which CMS finalized a NCD in October 2014. The Parallel Program was designed to reduce the time between FDA approvals and Medicare national coverage and, here, CMS issued its proposed NCD determination on November 30, 2017, the same date that FDA extended approval for the FoundationOne CDx test and within six months of the FDA’s receipt of the product application.

NCD Coverage Criteria

NGS is a technology that reads the order of nucleotide molecules on DNA and provides detailed information on multiple types of genetic alterations simultaneously. The NGS tests can help diagnose and identify patients with certain genetic mutations who can potentially benefit from specific cancer treatment, including FDA-approved chemotherapies, and thus assist patients and their physicians in making more informed treatment decisions. Results from the tests can also be used to determine whether a patient is eligible to participate in cancer clinical trials.

The final NCD defines the covered patient criteria as well as the covered test criteria. Specifically, the NCD for the NGS test provides one-time Medicare coverage solely for patients with either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer who have decided to seek further cancer treatment. In addition, the NCD extends coverage to repeat testing for a patient, but only when the patient has a new primary cancer diagnosis. Early-stage cancers are not covered.

A covered NGS diagnostic laboratory test must have:

- FDA approval or clearance as a companion in vitro diagnostic;
- an FDA approved or cleared indication for use in that patient’s cancer; and
- the results must be provided to the treating physician for management of the patient using a report template to specify treatment options.

For laboratory-developed and other tests that have not proceeded through the FDA-approval or clearance process, MACs may develop local coverage determinations for their jurisdictions. To be covered, the diagnostic
laboratory tests using NGS, whether or not they have undergone the FDA review process as a device, must be performed in a CLIA-certified laboratory, and must be ordered by a treating physician. In addition, for either national or local coverage, the Medicare patient must meet the above patient-specific requirements.

The NCD differs from the proposed coverage determination in a number of important ways. CMS extended coverage to advanced stage III cancers, rather than limiting coverage for advanced cancers to stage IV. Also, CMS did not finalize its proposal to use coverage with evidence development (CED) for NGS tests that have not obtained FDA approval as a companion diagnostic. Under CED, coverage would have been conditional, and would require data-gathering while evidence is continuing to be developed on health outcomes. In addressing the proposal, many commenters reported that they are already developing or have developed the evidence to demonstrate that these diagnostic laboratory tests using NGS improve health outcomes for Medicare beneficiaries with cancer, or are equipped to conduct their own studies to generate evidence that use of the test guides management and treatment, and improves health outcomes for the Medicare population. CMS removed the CED requirement, and encouraged the continuation and publication of the results of these studies, especially regarding overall survival, progression free survival, objective response, and patient reported outcomes relevant to the quality of life for Medicare beneficiaries.

**Additional Implications**

Given the fast-paced development in this area, and far-reaching implications for laboratory-developed tests generally, CMS and MAC acceptance of evidence for Medicare coverage purposes is closely watched. Although some changes were made to the CMS proposal, we expect to see further refinements in coverage criteria as more evidence is developed with respect to the role of NGS in shaping management of cancer treatments. In the interim, given the role of the Medicare program in shaping payor coverage policies for new technologies, companies may want to consider the advantages of going through the FDA review process in order to meet the national coverage criteria, especially in light of the benchmark role CMS policies play when other health plans develop their coverage policies.

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