

CMS Proposes Next Generation Sequencing Coverage for Medicare Beneficiaries with Advanced Cancer

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Last month, the U.S. Food and Drug Administration (“FDA”) approved the FoundationOne CDx, a next generation sequencing device (“F1CDx™”). Shortly after announcing FDA approval, CMS received a formal request (See: <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id290.pdf>) to establish coverage for comprehensive genomic profile testing for the management of cancer patients with solid, metastatic tumors (including Stage IV and recurrent tumors) with F1CDx™.

Next generation sequencing provides detailed information on multiple types of genetic alternations simultaneously, providing a more comprehensive genetic profile of cancer and information relevant to potential cancer treatments. Providers and patients believe the technology holds potential for personalized cancer therapy.

CMS is soliciting public comment relevant to the request through December 29, 2017.

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