

# CMS proposes to expand coverage for Next Generation Sequencing tests for certain cancer patients

November 1, 2019

On Tuesday, October 29, CMS issued a “Proposed Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer” ([Proposed Decision Memo](#)) that would expand Medicare coverage of FDA approved NGS lab tests for patients with ovarian or breast cancer that may be caused by hereditary factors, regardless of cancer stage. It also offers Medicare Administrative Contractors (MACs) greater discretion over coverage of NGS tests that are not FDA approved or cleared for certain patients with diagnoses other than breast and ovarian cancer.

NGS tests are laboratory tests that can be used to identify specific mutations in a patient’s own DNA (germline) or in the DNA of a cancer (somatic) and may thereby inform treatment of the patient’s cancer. The Proposed Decision Memo would expand Medicare coverage of these NGS tests for certain patients with cancer, which is currently limited by the [National Coverage Determination](#) (NCD) that CMS issued in March 2018. The current NCD (1) offers nationwide coverage of NGS testing for patients with “recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer,” if the NGS test is FDA approved or cleared as a companion in vitro diagnostic; and (2) gives MACs the discretion to develop Local Coverage Determinations (LCDs) for NGS tests that aren’t FDA cleared or approved as companion diagnostics for patients with such cancers. (Our summary of the March 2018 NCD is [here](#).)

In the Proposed Decision Memo, CMS acknowledges that it received objections to the current NCD’s limitations, many of which centered on the NCD’s restriction of coverage to patients with “recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer.” In addition, CMS received critical comments from many medical and patient advocacy groups after some MACs revised their existing LCDs to preclude coverage of germline testing for patients with earlier stage cancers in order to align them with the NCD. In response, CMS revisited the NCD and solicited comments to further analyze the clinical evidence, and concluded that use of NGS has clinical benefits beyond the limits established in the current NCD. That conclusion led to the current proposal.

**Proposal: NGS coverage for patients with inherited breast and ovarian cancer regardless of stage; MACs may cover NGS for other inherited cancers under an LCD**

The Proposed Decision Memo would expand Medicare coverage of NGS tests for patients diagnosed with **ovarian or breast cancers who have clinical indications or risk factors for inherited mutations associated with those cancers, regardless of the stage** of the patient's cancer. As under the current NCD, the proposed revision would require that the test be approved or cleared by FDA for use in that patient's cancer, that the results of the diagnostic test be provided to the treating physician with a template to specify treatment options, and that the test be performed in a CLIA-certified laboratory.

The revised NCD would cover NGS testing for a patient who:

- Has ovarian or breast cancer,
- Has clinical indications for germline (inherited) testing,
- Has risk factors for germline (inherited) breast or ovarian cancer, and
- Has not been previously tested using NGS.

In addition, CMS would continue to allow MACs to cover NGS testing for patients diagnosed with **cancers other than ovarian or breast cancer**, if the patient has clinical indications for inherited cancer testing and risk factors for that inherited cancer, and has not been previously tested using NGS. As with the proposed national coverage for ovarian and breast cancer, the Proposed Decision Memo would allow MACs to establish local coverage of NGS testing for other cancers **regardless of the stage** of the patient's cancer. CMS reasoned that it is best to maintain MACs' "discretion to make coverage decisions on diagnostic uses of NGS testing for patients with inherited cancers based on new evidence that may arise."

The Proposed Decision Memo would not extend coverage of NGS testing as a preventive service to patients who have not been diagnosed with cancer. CMS is permitted to develop NCDs to cover "additional preventive services" that are not specifically identified in the statute, have a grade of A or B from the United States Preventive Services Task Force (USPSTF), and are appropriate for Medicare beneficiaries. Genetic testing for breast cancer susceptibility 1 and 2 (BRCA1/2) mutations has such a recommendation and could be addressed through a future NCD.

The Proposed Decision Memo opens the way for national coverage of FDA-approved NGS tests for patients with ovarian and breast cancer that may be associated with an inherited mutation, and leaves room for those offering other NGS tests to seek coverage from MACs under an LCD. Comments on the Proposed Decision Memo must be submitted to CMS by November 28, and CMS expects to finalize the revised NCD on January 27, 2020. If you have questions about reimbursement or FDA approval of NGS tests for cancer, or if you are interested in submitting a comment to CMS, please contact any of the authors or the Hogan Lovells lawyer with whom you regularly work.

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