

## **Medicare Finalizes Updated Coverage of Next Generation Sequencing-based Tests for Inherited Breast and Ovarian Cancers**

On January 27, 2020, CMS announced it had finalized a national decision to cover FDA-approved Next Generation Sequencing (NGS) testing in patients with all stages of germline breast or ovarian cancer.

Although the agency has covered NGS for certain advanced cancers since 2018, the policy verbiage was viewed as confusing and interpreted as preventing coverage for early stage cancer patients. CMS subsequently reopened that coverage decision for reevaluation and in October, 2019, released its *Proposed Decision Memo* stating its new position on the testing and its application. A 30-day public comment period followed, after which CMS was expected to publish its final coverage decision.

In case you missed it, you can review a summary of the background and the proposed policy details in our November 2019 White Paper, "[Next Generation Sequencing for Cancer Patients: Will Medicare Clear the Confusion with Its New Proposed Decision Memo?](#)"

The final **National Coverage Determination (NCD) CAG-00450R** retains much of the intent of the proposed version with a few notable points:

1. The proposed policy limited coverage to patients who had not been previously tested using NGS. The final policy amends this statement to say that eligible patients must not have been previously tested "with the same germline test using NGS for the same germline genetic content."
2. The NCD remains specific to breast and ovarian cancers.
3. The NCD only applies to diagnostic lab tests using NGS for somatic and germline cancer.
4. Coverage of diagnostic lab tests using NGS for RNA sequencing and protein analysis, or for any non-cancer conditions (e.g., infectious disease and heart disease) will be at the discretion of the Medicare Administrative Contractors (MACs).

Access the full Decision Memo at:

<https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=296>