Hogan Lovells

CMS expands national coverage of Next Generation Sequencing tests for breast, ovarian cancer patients

31 January 2020

On Monday, 27 January, the Centers for Medicare & Medicaid Services (CMS) finalized its proposal to expand national coverage of the U.S. Food and Drug Administration (FDA)-approved or -cleared laboratory tests using next generation sequencing (NGS) for patients with breast or ovarian cancer at any stage, who have a risk factor and clinical indication for germline (inherited) ovarian or breast cancer. The final National Coverage Determination (NCD) mostly mirrors the October 2019 proposal, except that it loosens the proposed coverage requirement that a patient must not have been previously tested using NGS. The final NCD declines to expand national coverage to NGS tests for other types of earlier stage cancer, and to NGS tests that are not FDA-approved or -cleared, but gives Medicare Administrative Contractors (MAC) discretion to determine coverage of other NGS tests for patients with germline cancers when certain criteria are met.

CMS first issued an NCD for NGS tests for advanced cancer in March 2018, but then proposed changes to that policy in October 2019, in response to pushback regarding the narrow scope, and CMS' interpretation that it only applied to somatic (acquired) and not germline (inherited) cancers (our summary of the March 2018 NCD is online here). This revised NCD finalizes most of the elements of the October proposed decision memo (Proposal, summarized here), as it (1) expands national Medicare coverage of FDA-approved or -cleared NGS tests for patients with ovarian or breast cancer at any stage that may be caused by hereditary factors, and (2) offers MACs greater discretion to provide coverage of NGS tests that are not FDA-approved or -cleared for certain patients with diagnoses other than breast and ovarian cancer (again, regardless of cancer stage) when the patient has a clinical indication and risk factor for germline cancer.

The revised NCD now provides the following:

For somatic (acquired) cancer

NGS tests will be covered nationally when ordered by the treating physician and performed in a Clinical Laboratory Improvement Amendments (CLIA)-certified lab, when all of the following conditions are met:

- The patient has:

  - Recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer; and
  - Has not been previously tested with the same test using NGS for the same cancer genetic content; and
  - Has decided to seek further cancer treatment.
- The test using NGS must be FDA-cleared or -approved as a companion in vitro diagnostic; and an FDA-approved or -cleared indication for use in that patient's cancer; and results must be provided to the treating physician for the management of the patient.

MACs may determine coverage of NGS tests that are not FDA-cleared or -approved if they are performed in a CLIA-certified lab for patients with advanced cancer who have decided to seek further treatment and have not previously been tested with the same test using NGS for the same cancer genetic content.

For germline (inherited) cancer

NGS tests will be **covered nationally** when ordered by the treating physician and performed in a CLIA-certified lab, when all the following conditions are met:

- The patient has:
  - Ovarian or breast cancer (at any stage); and
  - A clinical indication for germline testing for hereditary breast or ovarian cancer; and
  - A risk factor for germline breast or ovarian cancer; and
  - Not previously been tested with the same germline test using NGS for the same germline genetic content.

MACs **may determine coverage** of NGS for germline cancer using tests that are not FDA-cleared or -approved if they are performed in a CLIA-certified lab, when the patient has:

- Any cancer diagnosis; and
- A clinical indication for germline testing of hereditary cancers; and
- A risk factor for germline cancer; and
- Has not been previously tested with the same germline test using NGS for the same germline genetic content.

Proposed vs. final NCD

One important change between the Proposal and final NCD is that CMS loosened the proposed coverage requirement that the patient has "not been previously tested using NGS." Instead, the final NCD merely requires that the patient has "not been previously tested with the same germline test using NGS for the same germline genetic content."

Some of the 43 comments on the Proposal objected to the coverage requirement that the test be approved or cleared by FDA for use in that patient's cancer, as no FDA-approved or -cleared NGS test currently meets the NCD's requirements for national coverage for germline analysis. In response, while CMS kept the criteria to require FDA clearance or approval for national coverage of germline NGS tests for breast and ovarian cancer patients, the final NCD gave MACs the ability

to establish local coverage for all NGS tests for patients with a risk factor and clinical indication for germline cancer.

The final NCD points out that "many" comments suggested NGS tests for other cancers also should be nationally covered, but CMS declined to expand coverage to earlier stage cancers other than breast and ovarian, citing insufficient evidence of clinical utility.

In a press release announcing the Decision, CMS Administrator Seema Verma praised NGS testing as providing "clinically valuable information to guide patients and physicians in developing a personalized treatment plan."

If you have questions about coverage and reimbursement or FDA approval of NGS tests for cancer, please contact any of the authors or the Hogan Lovells lawyer with whom you regularly work.

Contacts

Helen R. Trilling
Senior Counsel, Washington, D.C.
T +1 202 637 8653
helen.trilling@hoganlovells.com

Ronald L. Wisor, Jr.
Partner, Washington, D.C.
T +1 202 637 5658
ron.wisor@hoganlovells.com

Beth L. Roberts
Partner, Washington, D.C.
T +1 202 637 8626
beth.roberts@hoganlovells.com

Elizabeth (Beth) Halpern
Partner, Washington, D.C.
T +1 202 637 8609
elizabeth.halpern@hoganlovells.com

Brooke Bumpers
Counsel, Washington, D.C.
T +1 202 637 5800
brooke.bumpers@hoganlovells.com