EPSTEIN BECKER GREEN | Health Care & Life Sciences

CLIENT ALERT

Medicare's Proposed National Coverage Determination: Expanding Access to Genetic Screening Tests for Certain Ovarian and Breast Cancers

By Gail H. Javitt, Robert E. Wanerman, and Lesley R. Yeung

November 2019

On October 29, 2019, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed decision memo with a national coverage determination ("NCD") that would allow for Medicare coverage of next-generation sequencing ("NGS") as a diagnostic laboratory test for ovarian and breast cancers when certain conditions are met.[1] The proposed NCD would revise and expand the scope of the current Medicare NCD related to NGS testing of somatic (tumor) and germline (inherited) gene mutations for patients with advanced cancer that was originally adopted by CMS on March 16, 2018 (hereinafter "Advanced Cancer NCD").[2] Despite the recent adoption of an NCD related to NGS testing, CMS initiated the national coverage analysis process again this past spring specifically to reconsider the evidence available for tests of germline (inherited) gene mutations that are used to identify those with hereditary cancer who may benefit from targeted treatments.[3] Interested stakeholders have until **November 28, 2019,** to submit comments on CMS's newly issued proposed decision memo with NCD.

What Is NGS Testing?

NGS is a laboratory testing method that enables rapid sequencing of large sections of an individual's genome (e.g., DNA) derived from a patient's specimen (e.g., blood or saliva). The increased efficiency and reduced cost of NGS has made it feasible for laboratories to analyze large regions of DNA and to deliver a substantial amount of patient genetic data to physicians. In the cancer context, NGS is increasingly used to sequence both

[1] *See* CMS, Proposed Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R) (Oct. 29, 2019), *available at* https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=296.

[2] Medicare National Coverage Determinations Manual (Pub. 100-03), Chap. 1, Part 2 (Sections 90 – 160.26), Coverage Determinations, § 90.2 (Rev. 215, 04-10-19), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf.

[3] *See* CMS, National Coverage Analysis (NCA) Tracking Sheet for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R) (Apr. 29, 2019), *available at* https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=296&NcaName=Next+Generation+Sequencing+(NGS)+for+Medicare+Beneficiaries+with+Advanced+Cancer&ExpandComments=n&bc=AAAAAAAAAQAA&.

tumor (somatic) DNA and relevant regions of the patient's own (germline) DNA in order to inform the physician's treatment plan, including the selection of therapeutic agents.[4]

Background: How Is NGS Testing Currently Covered by Medicare?

The 2018 Advanced Cancer NCD authorized Medicare coverage for NGS testing as a diagnostic laboratory test under specified conditions. Coverage is limited to patients with recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer who have not been previously tested using the same NGS test for the same primary diagnosis of cancer and who have decided to seek further cancer treatment (e.g., therapeutic chemotherapy). In addition, the NGS test must have received U.S. Food and Drug Administration ("FDA") approval or clearance as a companion in vitro diagnostic ("IVD") with an indication for use in the patient's cancer. Finally, testing must be performed in a CLIA-certified laboratory, and test results must be provided to the treating physician for management of the patient using a report template to specify treatment options.[5]

The Advanced Cancer NCD also allowed for coverage of NGS tests that are not FDA-approved or cleared companion IVDs at the discretion of the local Medicare Administrative Contractors ("MACs").[6] However, the NCD did not provide any criteria that the MACs should use to make a coverage decision for an individual NGS test. Nevertheless, the MACs have the option to cover NGS tests on a case-by-case basis or to issue their own local coverage determinations ("LCDs"), which could range from fully positive to fully negative coverage for additional NGS tests.

How Is CMS Proposing to Expand Coverage for NGS Testing?

The October 29, 2019, proposed decision memo would expand coverage for NGS testing related to the diagnosis of ovarian and breast cancers. Specifically, CMS proposes to maintain the current NCD language described above and to authorize coverage for NGS testing of germline (inherited) gene mutations in patients with ovarian or breast cancer who have risk factors and clinical indications for germline (inherited) cancer and who have not previously been tested using NGS. Additionally, the NGS test would need to be FDA approved or cleared with an indication for use in the patient's cancer, ordered by the patient's treating physician, and performed in a CLIA-certified laboratory. Test results would need to be provided to the treating physician for management of the patient using a report template to specify treatment options.

---

[4] *See generally* Epstein Becker Green Client Alert, Obstacles in the Path? Medicare's National Coverage Determination on Next-Generation Sequencing Has Significant Implications for Precision Medicine (Mar. 2018), *available at* https://www.ebglaw.com/content/uploads/2018/03/HCLS-Client-Alert-Medicare-NCD-on-NGS1.pdf.

[5] *Id.*

[6] The MACs are authorized under Sections 1842(a) and 1874A of the Social Security Act to perform various payment functions for the Medicare program, including, for example, the review, processing, and adjudication of Medicare claims; determining whether specific services are reasonable and necessary and, therefore, covered under Medicare; and developing local coverage determinations.

Similar to the Advanced Cancer NCD, CMS also proposes to allow the local MACs to determine coverage for other NGS tests that are not FDA approved and that are used for patients with a cancer diagnosis other than breast or ovarian cancer.

Why Has CMS Proposed to Make This Change?

The Advanced Cancer NCD raised concerns from laboratory and other stakeholders when it was published last year. They worried that the requirement for FDA approval would adversely affect access to NGS testing, since most laboratories offer NGS as a "laboratory developed test" ("LDT") that does not require FDA approval. Further, they argued that the additional requirement for an indication-specific FDA approval suggested that NGS data cannot usefully inform clinical decision making in the absence of a specific FDA-approved therapy tied to testing. Although FDA left open the local MAC coverage pathway, stakeholders expressed concern that its unpredictability would deter or delay the development of new NGS tests. Thus, both the NCD and MAC pathways were viewed as a barrier that could delay or deter the development of new NGS tests.[7]

While the proposed NCD expansion does not address these concerns, it does respond to another concern raised by stakeholders,[8] namely, that the Advanced Cancer NCD limited *germline* testing to patients with advanced cancer, even though the NCD was issued in response to a request by the developer of an FDA-approved NGS test for somatic mutations.[9] For example, women with inherited BRCA mutations and who had early-stage cancer were excluded from the NCD. Some MACs that had covered NGS to identify hereditary cancer genes in patients with early stage or previous history of cancer changed their policies to exclude coverage as a result of the NCD.[10]

Stakeholders argued that patients with early-stage cancer need germline NGS testing to assess their risk for cancer and to inform treatment strategies to prevent cancer progression, relapse, or recurrence, as well as to alert family members who might be at risk.

---

[7] *See* Javitt, G. H. and Wanerman, R. E., Health Affairs Blog, CMS Coverage Decision May Raise Barriers to Precision Cancer Medicine and Reduce Incentives for Evidence Development (Mar. 22, 2018), *available at* https://www.healthaffairs.org/do/10.1377/hblog20180322.833957/full/.

[8] *See e.g.*, Letter to Seema Verma (Jan. 31, 2019), *available at* https://www.amp.org/AMP/assets/File/advocacy/Group_Stakeholder_Letter_NGSNCD-FINAL-1-31-2019.pdf?pass=52.

[9] Specifically, the final decision memo states that "this decision is not applicable to all diagnostic laboratory tests using NGS, but rather to a unique diagnostic laboratory test that uses NGS for patients with cancer to manage the patient's cancer by identifying either targeted therapies with known efficacy or in some cases, eligibility for a cancer clinical trial." *See* CMS, Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N) (Mar. 16, 2018), *available at* https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=290&bc=AAAAAAAAACAA&.

[10] *See e.g.*, Palmetto GBA, Local Coverage Determination (LCD): MolDX: BRCA1 and BRCA2 Genetic Testing (L36082), *available at* https://www.genomeweb.com/sites/default/files/local_coverage_determination_for_moldx_brca1_and_brca2_genetic_testing_l36082.pdf.

CMS responded to these concerns by reopening the Advanced Cancer NCD, and has proposed coverage for NGS testing specific to germline (inherited) mutations for patients with breast and ovarian cancer (regardless of the stage of the disease).

How Could CMS's Conclusions Impact Coverage for Other Precision Diagnostic Tests?

CMS's broad application of the coverage restrictions included in the Advanced Cancer NCD has raised questions about how far the agency is willing to go to cover precision diagnostics, which is an emerging approach for disease prevention and treatment that is able to target care based on an individual's genes, environment, and lifestyle. CMS's recent efforts to reopen the Advanced Cancer NCD and reconsider coverage for certain NGS testing provides some indication of the agency's support and willingness to consider emerging clinical evidence in developing national coverage policies. The proposed decision memo acknowledges the clinical evidence supporting the use of NGS as a diagnostic tool for breast and ovarian cancer to "identify the germline mutations most likely to be targeted by a treatment regimen tailored to certain germline mutation" and thereby improve health outcomes of Medicare beneficiaries. According to CMS, use of NGS in this context "has utility for patients in the discovery of new targeted therapies for inherited cancers and in the physician management of inherited cancers of the breast and ovary in Medicare beneficiaries." Further, CMS has proposed to maintain the MACs' discretion to make coverage decisions on the diagnostic uses of NGS testing for patients with other inherited cancers because CMS believes that the evidence related to other cancers is rapidly developing.

On the other hand, the requirement for an indication-specific FDA approval sets a high bar that could deter the development of new LDT-based NGS tests. NGS appears to view FDA premarket review as the sole pathway for test validation and clinical evidence development, thereby excluding LDT-based tests from coverage. Although the proposed NCD leaves the MAC pathway open, it is unclear how successful that pathway will be in practice.

Interested stakeholders should continue to monitor CMS developments related to NGS testing, and consider submitting comments in response to the proposed decision memo.

* * *

This Client Alert was authored by **Gail H. Javitt, Robert E. Wanerman,** *and* **Lesley R. Yeung.** *For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

About Epstein Becker Green
Epstein Becker & Green, P.C., is a national law firm with a primary focus on health care and life sciences; employment, labor, and workforce management; and litigation and business disputes. Founded in 1973 as an industry-focused firm, Epstein Becker Green has decades of experience serving clients in health care, financial services, retail, hospitality, and technology, among other industries, representing entities from startups to Fortune 100 companies. Operating in locations throughout the United States and supporting domestic and multinational clients, the firm's attorneys are committed to uncompromising client service and legal excellence. For more information, visit www.ebglaw.com.

If you would like to be added to our mailing list or need to update your contact information, please contact Kristen Vetula at kvetula@ebglaw.com or 202-861-1845.