

Next-Generation Sequencing for Cancer Patients: Will Medicare Clear the Confusion With Its New Proposed Decision Memo?

BACKGROUND

Prior to coverage of Next-Generation Sequencing (NGS) testing at the national level, many Medicare Administrative Contractors (MACs) already had in place Local Coverage Determinations (LCDs) providing coverage of NGS to screen early stage cancer patients for mutations associated with inherited cancer syndromes such as BRCA and Lynch syndrome. The MACs requested that Medicare issue a National Coverage Determination specifically for patients with advanced cancer, limited to somatic-based testing.

In March 2018, Medicare finalized coverage of NGS for patients with advanced cancer through its National Coverage Determination NCD 90.2; however, Medicare instructed MACs to apply it to both somatic and germline NGS testing through expected alignment of the respective NCD and LCDs. Because NCDs supersede LCDs this essentially was interpreted as eliminating coverage for early stage cancer patients to access germline NGS testing.

Responding to intense industry pressure, CMS ultimately reopened the coverage decision for reevaluation and public comment.

On October 29, 2019, CMS released its [Proposed Decision Memo for Next Generation Sequencing \(NGS\) for Medicare Beneficiaries with Advanced Cancer \(CAG-00450R\)](#) stating its new proposed position. According to the Decision Summary, CMS finds:

1. Evidence is sufficient to expand coverage of NGS as a diagnostic lab test when performed in a CLIA-certified lab when ordered by a treating physician and when all of the following requirements are met:

The patient has:

- Ovarian or breast cancer
 - Clinical indications for germline (inherited) testing
 - Risk factors for germline (inherited) breast or ovarian cancer and
 - Not been previously tested using NGS
2. Medicare Administrative Contractors (MACs) may determine coverage of other NGS as a diagnostic lab test when performed in a CLIA-certified lab, when ordered by a treating physician, when results are provided to the treating physician for management of the patient and when all of the following conditions are met:

The patient has:

- A cancer diagnosis other than breast or ovarian cancer
- Clinical indications for germline (inherited) testing
- Risk factors for germline (inherited) cancer other than inherited breast or ovarian cancer and
- Not been previously tested using NGS

There is a 30-day public comment period on this proposed decision that can be accessed [here](#). Be sure to select the Comment Period of 10/29/2019 – 11/28/2019 to enter and/or view the comments specific to this latest proposed decision.

The final coverage decision is expected to be published in January 2020. APS will provide additional information on this topic as released by CMS. Should you have any questions, please contact your Practice Manager.

Helpful Links:

National Coverage Analysis Tracking Sheet

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

Proposed Decision Memo

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

Public Comment Page

[https://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=296&NcaName=Next+Generation+Sequencing+\(NGS\)+for+Medicare+Beneficiaries+with+Advanced+Cancer&ExpandComments=n&bc=AAAAAAAAACAA&](https://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=296&NcaName=Next+Generation+Sequencing+(NGS)+for+Medicare+Beneficiaries+with+Advanced+Cancer&ExpandComments=n&bc=AAAAAAAAACAA&)