# 60+ health care groups urge CMS to maintain coverage for medically necessary cancer testing

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Leading health care companies and organizations representing patients, providers, academic medical centers, laboratories, and diagnostic manufacturers urged the Centers for Medicare and Medicaid Services (CMS) to revise its interpretation of the National Coverage Determination (NCD) for Next Generation Sequencing (NGS). In a letter to CMS Administrator Seema Verma, 63 organizations expressed serious concerns that the overly broad interpretation will restrict patient access to medically necessary and relevant clinical tests and adversely impact cancer care and outcomes.

CMS' latest guidance directly undermines beneficiaries' coverage as finalized in last year's NCD. NGS-based testing is now the standard of care for cancer patients, and the current interpretation implies NGS-based testing will become non-covered for many Medicare beneficiaries. This has a direct result on beneficiaries' access and coverage to essential testing that can make a fundamental difference in their treatment.

In particular, those with early-stage cancer who may have a genetic predisposition based on family history or other acceptable criteria will not be eligible for testing using NGS-based methods. Restricting patients with early-stage cancers from accessing hereditary testing may lead to poorer outcomes as they are not receiving optimal therapy based on their genetic status.

"It is essential that CMS unequivocally maintain coverage for medically necessary NGS-based tests. Imposing broad restrictions on standard of care testing will have serious consequences for Medicare beneficiaries and negatively impact their care," said Julie Khani, President of the American Clinical Laboratory Association.

"CMS' interpretation of the NGS NCD contradicts and reverses previously established policies. The NCD supersedes existing local coverage determinations that provide crucial coverage of NGS-based genetic testing for mutations associated with inherited cancer syndromes—like BRCA mutations and Lynch syndrome—in patients without advanced cancer," said Sue Friedman, Executive Director of FORCE: Facing Our Risk of Cancer Empowered. "This action will harm patients! We are extremely disappointed that there was never an opportunity for patient advocacy groups to formally comment or discuss the implementation of this policy and frustrated that these medically necessary tests are now not eligible for Medicare coverage."

"AMP is committed to working with key stakeholders to preserve broad patient access to the thousands of clinically- and analytically-validated NGS-based testing for cancer and other conditions that benefit patients each and every day," said Mary Steele Williams, Executive Director of Association for Molecular Pathology. "Rather than creating additional barriers, we urge CMS to consider the collective comments from this diverse community of health care organizations and reinstate coverage for these medically necessary hereditary cancer tests. Without precision diagnostics, there is no precision medicine."

**More information:** To view the full letter and list of undersigned organizations, please visit www.amp.org/NGSNCDLetter.

Provided by Association for Molecular Pathology

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