

Proposed NGS changes jeopardize patient care

Jan. 24, 2018—Citing the potential severe negative consequences to Medicare patients, the [College of American Pathologists](#) opposed a draft national coverage determination policy for next-generation sequencing and urged the [Centers for Medicare & Medicaid Services](#) to make substantial changes.

On Nov. 30, 2017 the CMS proposed a wide-ranging NCD that would set limits on all current and future uses of NGS technologies in all Medicare patients with advanced cancer. The CAP responded to the proposed NCD with a [Jan. 17 letter](#) detailing its concerns for potential impacts on Medicare patients.

“The implementation of the proposed NCD criteria would have profound adverse and immediate consequences for access to therapies by Medicare beneficiaries, and treating physician’s ability to order medically necessary tests,” the CAP stated in the letter. “Future development of test-based cancer therapies would also be impacted.”

In this proposed coverage, the CMS would cover NGS testing for patients with advanced cancer as long as the NGS test is run by a laboratory or platform that has been FDA approved or cleared and in a disease state for which there is an FDA-approved companion diagnostic and drug.

If a test is run by a laboratory that has been cleared or run as an FDA-approved in vitro diagnostic (not a companion in vitro diagnostic) in a patient with a disease for which there is FDA-approved companion diagnostic and drugs, then the CMS will pay for the test if data is collected as part of a prospective registry under coverage with evidence development. The CMS will pay for NGS testing for patients within a NIH-NCI National Clinical Trial Network clinical trial, as part of coverage with evidence development.

As reported in the Jan. 23 issue of *STATLINE*, the CAP is concerned that the proposed NCD constitutes an anomalous attempt to specify the medically reasonable and necessary clinical utilization of an entire family of methodologies, rather than more appropriately addressing the detection of specific genetic mutations that are clinically relevant. The implementation of the proposed NCD criteria would have profound adverse and immediate consequences for access to therapies by Medicare beneficiaries and treating physician’s ability to order medically necessary tests.

The CAP wants to ensure that patients will have minimal impact from the scope and framework of the NCD as it will restrict and deny patients and Medicare beneficiaries’ access to care.

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