

PUBLICATION

Precision Medicine Advances: Medicare Coverage of Next Generation Sequencing Testing

April 12, 2018

Medicare recently released a new national coverage determination (NCD) that addresses certain diagnostic laboratory tests using Next Generation Sequencing (NGS) for patients with advanced cancer. NGS technology has made it possible to decode the entire human genome and provides the potential to enhance individualized patient care, as this technology can identify rare genetic mutations and variations, including cancer-causing genetic mutations. The NGS oncology tests can provide patients and providers with a more comprehensive genetic profile of cancer and information relevant to potential cancer treatments. The NCD is a significant step forward in the advancement of personalized or precision medicine as limited Medicare reimbursement can hinder the development and growth of precision medicine.

The NCD limits coverage to those NGS tests approved by the U.S. Food and Drug Administration (FDA) or cleared as a companion in vitro diagnostic, meaning the test provides information that is essential for the safe and effective use of a specific therapeutic product and identifies patients most likely to benefit from the therapy. The requirement that NGS tests be approved or cleared by the FDA is a reflection that, historically, these types of tests were not covered because they lacked scientific validity. Under the NCD, the test must be performed in a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory and ordered by the patient's treating physician. Additionally, the NCD requires that NGS test results be presented to the physician using a report template that specifies treatment options in order for the physician to manage patient care. The NCD does not limit the number or specific type of cancers eligible for coverage. CMS believes that specifying coverage criteria for each cancer diagnosis will stifle innovative approaches to NGS testing. Currently, the NCD only covers four specific FDA approved companion diagnostic test using NGS. It is left to the discretion of the Medicare Administrator Contractor (MAC) whether other diagnostic lab tests using NGS will be covered.

In order to receive the NGS test, the patient must have either recurrent, relapsed, refractory, metastatic, or advanced Stage III or IV cancer. The patient won't be covered for multiple NGS tests for the same primary diagnosis as coverage for the same NGS test will only occur when a new primary cancer diagnosis has been made. If the patient has not been diagnosed with a new cancer, a NGS test is coverable but only if a different NGS test is used than what has been used previously.

Baker Donelson Comments

For many years, this type of testing was denied because the impact on treatment was speculative. Medicare denied coverage where the results of the testing did not alter or impact the treatment offered. Labs had to appeal for coverage on a claim-by-claim basis. Medicare coverage of NGS tests are critical for the advancement of precision medicine and the NCD is a step in the right direction. Providers should carefully review the NCD requirements as failure to meet the requirements will negatively affect reimbursement.