



National Coverage Determination (NCD90.2): Next Generation Sequencing (NGS)

MLN Matters Number: MM10878 **Revised**

Related Change Request (CR) Number: 10878

Related CR Release Date: **April 10, 2019**

Effective Date: March 16, 2018

Related CR Transmittal Number: **R215NCD**

Implementation Date: April 8, 2019 -A/B
MACs

Note: We revised this article on April 16, 2019, to reflect the revised CR 10878 issued on April 10. CMS revised the CR to add missing CPT codes on the diagnosis code attachments of the CR. In this article, we revised the CR implementation date, the CR release date, transmittal number, and the web address of the CR. All other information remains the same.

PROVIDER TYPE AFFECTED

This MLN Matters Article is for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10878 informs, effective March 16, 2018, the Centers for Medicare & Medicaid Services (CMS) covers diagnostic laboratory tests using next generation sequencing when performed in a Clinical Laboratory Improvement Amendments- certified laboratory when ordered by a treating physician and when specific requirements are met. Make sure your billing staffs are aware of this change.

This revision to the “Medicare National Coverage Determinations Manual” is a national coverage determination (NCD). NCDs are binding on MACs with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR Section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

BACKGROUND

Clinical laboratory diagnostic tests can include tests that, for example, predict the risk associated with one or more genetic variations. In vitro companion diagnostic laboratory tests

provide a report of test results of genetic variations and are essential for the safe and effective use of a corresponding therapeutic product. NGS is one technique that can measure one or more genetic variation as a laboratory diagnostic test, such as when used as a companion in vitro diagnostic test.

Patients with advanced cancer can have recurrent, relapsed, refractory, metastatic, and/or stages III or IV of cancer. Clinical studies show that genetic variations in a patient's cancer can, in concert with clinical factors, predict how each individual responds to specific treatments.

In application, a report of results of a diagnostic laboratory test using NGS (that is, information on the cancer's genetic variations) can contribute to predicting a patient's response to a given drug: good, bad, or none at all. Applications of NGS to predict a patient's response to treatment occurs ideally prior to initiation of the drug.

CMS reviewed the evidence for laboratory diagnostic tests using NGS in patients with cancer, and determined that such tests with analytical and clinical validity, and clinical utility, could also improve health outcomes for Medicare beneficiaries with advanced cancer. Therefore, CMS shall cover certain diagnostic laboratory tests using NGS when requirements are met.

Effective for claims with dates of service on or after March 16, 2018, CMS has determined that the evidence is sufficient to cover diagnostic laboratory tests that use NGS under specified conditions. CMS will cover such testing under the Medicare program for beneficiaries with recurrent, relapsed, refractory, metastatic cancer, or advanced stages III or IV cancer if the beneficiary has either not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician, and decided to seek further cancer treatment (for example, therapeutic chemotherapy). The test must be ordered by the treating physician, performed in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory, and have all the following requirements met:

- Food & Drug Administration (FDA) approval or clearance as a companion in vitro diagnostic;
- An FDA-approved or -cleared indication for use in that patient's cancer; and,
- Results provided to the treating physician for management of the patient using a report template to specify treatment options.

Additionally, MACs may determine coverage of other diagnostic laboratory tests using NGS for patients with cancer only when the test is performed in a CLIA-certified laboratory, ordered by the treating physician and the patient has:

- Either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; and,
- Either not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician; and,

- Decided to seek further cancer treatment (for example, therapeutic chemotherapy).

A diagnostic laboratory test using NGS is non-covered when cancer patients do not have the above-noted indications for cancer under either national or local coverage criteria.

ADDITIONAL INFORMATION

The official instruction, CR10878, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R215NCD.pdf>. Attachment 1 of CR10878 contains a list of covered clinical diagnostic laboratory tests using NGS and respective allowed ICD-10 diagnosis codes for the listed effective dates.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

DOCUMENT HISTORY

Date of Change	Description
April 16, 2019	We revised this article to reflect the revised CR 10878 issued on April 10. CMS revised the CR to add missing CPT codes on the diagnosis code attachments of the CR. In this article, we revised the CR implementation date, the CR release date, transmittal number, and the web address of the CR. All other information remains the same.
March 13, 2019	We revised the article to reflect the revised CR 10878 issued on March 6. In the article, we revised the CR implementation date, the CR release date, transmittal number, and the web address of the CR. All other information remains the same.
December 10, 2018	Initial article released.

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