



National Coverage Determination (NCD 90.2): Next Generation Sequencing (NGS) for Medicare Beneficiaries with Germline (Inherited) Cancer

MLN Matters Number: MM11837

Related Change Request (CR) Number: 11837

Related CR Release Date: September 11, 2020

Effective Date: January 27, 2020

Related CR Transmittal Number: R10346NCD

Implementation Date: November 13, 2020

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

This article, based on CR 11837, informs you about National Coverage Determination (NCD) 90.2, Next Generation Sequencing (NGS) for Medicare Beneficiaries with germline (inherited) cancer. Effective for dates of service on and after January 27, 2020, the Centers for Medicare & Medicaid Services (CMS) has determined that NGS, as a diagnostic laboratory test, is reasonable and necessary and covered nationally for patients with germline (inherited) cancer when performed in a CLIA-certified laboratory, when ordered by a treating physician, and when specific requirements are met. Make sure that your billing staffs are aware of these changes.

BACKGROUND

Clinical laboratory diagnostic tests can include tests that, for example, predict the risk associated with one or more genetic variations. NGS is one technique that can measure one or more genetic variations as a laboratory diagnostic test. NGS tests are a relatively new type of molecular diagnostic test that provides a more comprehensive method of processing much more genetic information and in some cases identification of a companion therapeutic drug treatment based on the results of the next generation sequencing test. In addition, NGS tests may create reports for oncologists that include interpretation of a patient's genetic profile, which may provide a prognosis, efficacy of specific treatments, and a review of relevant clinical publications. Germline mutations are a limited type of inherited mutations that may also lead to cancer.

Effective for services performed on or after January 27, 2020, CMS has determined that NGS as a diagnostic laboratory test is reasonable and necessary and covered nationally for patients with germline (inherited) cancer, when performed in a Clinical Laboratory Improvement

Amendments (CLIA)-certified laboratory, when ordered by a treating physician, and when **all** of the following requirements are met:

1. Patient has:
 - ovarian or breast cancer; and
 - a clinical indication for germline (inherited) testing for hereditary breast or ovarian cancer; and
 - a risk factor for germline (inherited) breast or ovarian cancer; and
 - not been previously tested with the same germline test using NGS for the same germline genetic content.
2. The diagnostic laboratory test using NGS must have **all** of the following:
 - the Food and Drug Administration (FDA)-approval or clearance; and
 - results provided to the treating physician for management of the patient using a report template to specify treatment options.

Effective for services performed on or after January 27, 2020, MACs may determine coverage of NGS as a diagnostic laboratory test for patients with germline (inherited) cancer only when the test is performed in a CLIA-certified laboratory, when ordered by a treating physician, when results are provided to the treating physician for management of the patient and when the patient has **all** of the following:

- **any** cancer diagnosis; and
- a clinical indication for germline (inherited) testing of hereditary cancers; and
- a risk factor for germline (inherited) cancer; and
- not been previously tested with the same germline test using NGS for the same germline genetic content.

NOTE: Please refer to CR 10878, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R215NCD.pdf> (A related article is at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/mm10878.pdf>.) and CR 11655, <https://www.cms.gov/files/document/r10193otn.pdf> for existing and additional coding when processing NGS-related claims. (A related article is at <https://www.cms.gov/files/document/mm11655.pdf>.)

ADDITIONAL INFORMATION

The official instruction, CR 11837, issued to your MAC regarding this change is available at <https://www.cms.gov/files/document/r10346ncd.pdf>.

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
September 15, 2020	Initial article released.

Disclaimer: Paid for by the Department of Health & Human Services. This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2019 American Medical Association. All rights reserved.

Copyright © 2013-2020, the American Hospital Association, Chicago, Illinois. Reproduced by CMS with permission. No portion of the AHA copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816. You may also contact us at ub04@healthforum.com

The American Hospital Association (the "AHA") has not reviewed, and is not responsible for, the completeness or accuracy of any information contained in this material, nor was the AHA or any of its affiliates, involved in the preparation of this material, or the analysis of information provided in the material. The views and/or positions presented in the material do not necessarily represent the views of the AHA. CMS and its products and services are not endorsed by the AHA or any of its affiliates.