

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 10346</b>	<b>Date: September 11, 2020</b>
	<b>Change Request 11837</b>

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

**I. SUMMARY OF CHANGES:** The purpose of this change request is to inform contractors that effective for dates of service on and 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 CLIA-certified laboratory, when ordered by a treating physician and when specific requirements are met.

The Federal government creates NCDs that are binding on the MACs who review and/or adjudicate claims, make coverage determinations, and/or payment decisions, and also binds quality improvement organizations, qualified independent contractors, the Medicare appeals council, and Administrative Law Judges (ALJs) (see 42 Code of Federal Regulations (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.)

**EFFECTIVE DATE: January 27, 2020**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: November 13, 2020**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	1/90/90.2/Next Generation Sequencing (NGS) for Medicare Beneficiaries with Germline (Inherited) Cancer

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question

and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Business Requirements**

**Manual Instruction**

# Attachment - Business Requirements

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**EFFECTIVE DATE: January 27, 2020**

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**IMPLEMENTATION DATE: November 13, 2020**

## **I. GENERAL INFORMATION**

**A. Background:** Clinical laboratory diagnostic tests can include tests that, for example, predict the risk associated with one or more genetic variations. Next Generation Sequencing (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.

**B. Policy:** 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, Medicare Administrative Contractors (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:

- 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.



Number	Requirement	Responsibility									
		A/B MAC		H H H	M A C	D M E	Shared-System Maintainers				Other
		A	B				F I S S	M C S	V M S	C W F	
11837.3	Contractors shall provide consensus recommendations to CMS in a final report uploaded into ECHIMP, under the Post Issued tab, Analysis Call Documents sub-tab, no later than 30 business days following the final meeting.	X	X								
11837.4	A/B MACs shall implement local edits in each respective jurisdiction until such time as CMS may determine shared edits to be appropriate, which will be relayed via a subsequent CR.	X	X								

**III. PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility						
		A/B MAC		H H H	M A C	D M E	C E D I	I
		A	B					
11837.5	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X					

**IV. SUPPORTING INFORMATION**

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:
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**Section B: All other recommendations and supporting information: N/A**

## **V. CONTACTS**

**Pre-Implementation Contact(s):** Kimberly Long, 410-786-5702 or Kimberly.Long@cms.hhs.gov (Coverage and Analysis Group) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis Coverage) , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis Group)

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

## **VI. FUNDING**

### **Section A: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**ATTACHMENTS: 0**

## **90.2 Next Generation Sequencing (NGS) for Patients with Somatic (Acquired) and Germline (Inherited) Cancer**

*(Rev.10346, Issued: 09-11-2020, Effective: 01-27-2020, Implementation :11-13-2020)*

### **A. General**

Clinical laboratory diagnostic tests can include tests that, for example, predict the risk associated with one or more genetic variations. In addition, 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. Next Generation Sequencing (NGS) is one technique that can measure one or more genetic variations as a laboratory diagnostic test, such as when used as a companion in vitro diagnostic test.

*This National Coverage Determination (NCD) is only applicable to diagnostic lab tests using NGS for somatic (acquired) and germline (inherited) cancer. Medicare Administrative Contractors (MACs) may determine coverage of diagnostic lab tests using NGS for RNA sequencing and protein analysis.*

### **B. Nationally Covered Indications**

#### **1. Somatic (Acquired) Cancer**

Effective for services performed on or after March 16, 2018, the Centers for Medicare & Medicaid Services (CMS) has determined that Next Generation Sequencing (NGS) as a diagnostic laboratory test is reasonable and necessary and covered nationally, 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:

- a. Patient has:
  - i. either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer; and
  - ii. *not been previously tested with the same test using NGS for the same cancer genetic content, and*
  - iii. decided to seek further cancer treatment (e.g., therapeutic chemotherapy).
- b. The diagnostic laboratory test using NGS must have:
  - i. Food & Drug Administration (FDA) approval or clearance as a companion in vitro diagnostic; and,
  - ii. an FDA-approved or -cleared indication for use in that patient's cancer; and,
  - iii. results provided to the treating physician for management of the patient using a report template to specify treatment options.

#### **2. Germline (Inherited) 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 CLIA-certified laboratory, when ordered by a treating physician and when all of the following requirements are met:*

- a. Patient has:
  - i. *ovarian or breast cancer; and,*
  - ii. *a clinical indication for germline (inherited) testing for hereditary breast or ovarian cancer; and,*

- iii. *a risk factor for germline (inherited) breast or ovarian cancer; and*
- iv. *not been previously tested with the same germline test using NGS for the same germline genetic content.*

b. *The diagnostic laboratory test using NGS must have all of the following:*

- i. *FDA-approval or clearance; and,*
- ii. *results provided to the treating physician for management of the patient using a report template to specify treatment options.*

### **C. Nationally Non-Covered *Indications***

#### **1. *Somatic (Acquired) Cancer***

Effective for services performed on or after March 16, 2018, NGS as a diagnostic laboratory test for patients with acquired (*somatic*) cancer are non-covered if the cancer patient does not meet the criteria noted in section B.1., above.

### **D. Other**

#### **1. *Somatic (Acquired) Cancer***

Effective for services performed on or after March 16, 2018, Medicare Administrative Contractors (MACs) may determine coverage of NGS as a diagnostic laboratory test for patients with *advanced* cancer only when the test is performed in a CLIA-certified laboratory, *when* ordered by a treating physician, and when the patient has:

- a. *either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; and,*
- b. *not been previously tested with the same test using NGS for the same cancer genetic content, and*
- c. *decided to seek further cancer treatment (e.g., therapeutic chemotherapy).*

#### **2. *Germline (Inherited) Cancer***

*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:*

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

*(This NCD last reviewed January 2020)*