

# Local Coverage Article: Billing and Coding: MoIDX: Minimal Residual Disease Testing for Colorectal Cancer (A58448)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
				Islands

# Article Information

## General Information

**Article ID**

A58448

**Article Title**

Billing and Coding: MoIDX: Minimal Residual Disease Testing for Colorectal Cancer

**Article Type**

Billing and Coding

**Original Effective Date**

10/18/2020

**Revision Effective Date**

N/A

**Revision Ending Date**

N/A

**Retirement Date**

N/A

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## **CMS National Coverage Policy**

N/A

## **Article Guidance**

### **Article Text:**

This Medicare contractor will provide limited coverage for ctDNA tests that detect minimum residual disease (MRD) in patients with a personal history of colorectal cancer.

Specifically, the enclosed evidentiary review is focused on the Signatera molecular residual disease assessment test, from here on called "Signatera," (Natera, Inc, San Carlos, CA). Other tests that demonstrate equivalent analytical and clinical validity as part of a comprehensive technical assessment (TA) will similarly attain coverage for indications that are supported by the evidence and intended use within scope of this policy.

This Contractor provides limited coverage for MRD testing in colorectal cancer when:

1. The conditions set by NCD 90.2 are fulfilled if NGS methodology is utilized (summarized: the patient has advanced cancer; plans on being treated for said cancer, and has not been previously been tested with the same test for the same genetic content) or are not applicable (the patient does not have cancer as defined below);
2. The patient has a personal history of colorectal cancer, the type and staging of which is within the intended use of the MRD test;
3. The identification of recurrence or progression of disease within the intended use population of the test is identified in the NCCN Guidelines as a condition that requires a definitive change in patient management;
4. The test is demonstrated to identify recurrence or progression before there is clinical or radiographical evidence of recurrence or progression; and demonstrates sensitivity and specificity comparable with radiographical evidence of recurrence. For colorectal cancer, it must have a sensitivity at least equivalent to and specificity that is significantly better than serial CEA monitoring OR demonstrate equivalence with another ctDNA MRD test that has demonstrated this measuring the same analytes. Test performance must be similar to established MRD tests including Signatera
5. The test satisfactorily completes a technical assessment that will review and confirm the analytical and clinical validity of the test.

MRD testing often requires two types of assays to be performed as part of the service. First, a sample is taken from tumor diagnostic material to establish a baseline tumor signature as defined by the test methodology. This is followed by a series assays run on blood to detect the presence or recurrence of tumor based on the measured biomarkers, expression, or other analytes over various timepoints. This series of assays comprises a single test when the patient is known to have cancer.

When the patient is NOT known to have cancer (specifically when there is no clinical, radiographical, or other

biological evidence that tumor cells remain post treatment and subsequently the patient is no longer being subjected to therapeutic interventions for cancer), a second kind of test may exist wherein a single additional timepoint may constitute a single test.

The evidentiary review is available upon request.

## Coding Information

### CPT/HCPCS Codes

#### Group 1 Paragraph:

N/A

#### Group 1 Codes:

CODE	DESCRIPTION
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE

### CPT/HCPCS Modifiers

N/A

### ICD-10 Codes that Support Medical Necessity

#### Group 1 Paragraph:

N/A

#### Group 1 Codes:

ICD-10 CODE	DESCRIPTION
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon

ICD-10 CODE	DESCRIPTION
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.1	Malignant neoplasm of anal canal

**ICD-10 Codes that DO NOT Support Medical Necessity**

N/A

**Additional ICD-10 Information**

N/A

**Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

**Revenue Codes:**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

**Other Coding Information**

N/A

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## Revision History Information

N/A

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# Associated Documents

## Related Local Coverage Document(s)

N/A

## Related National Coverage Document(s)

N/A

## Statutory Requirements URL(s)

N/A

## Rules and Regulations URL(s)

N/A

## CMS Manual Explanations URL(s)

N/A

## Other URL(s)

N/A

## Public Version(s)

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# Keywords

N/A