Billing and Coding Article

Article - Billing and Coding: MoIDX: MammaPrint (A54447)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

Article Information

General Information

Article ID

A54447

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Article Title

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Fee schedules, relative value units, conversion factors and/or related

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Billing and Coding	
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CMS National Coverage Policy

N/A

Article Guidance

Article Text

MammaPrint® *is a diagnostic test that analyzes the gene expression profile of FFPE breast cancer tissue samples to assess a patients' risk for distant metastasis.*

The test can be performed using either a FDA-cleared in vitro microarray assay or a next generation sequencing (NGS)-based assay. Each assay has been assigned a unique Z-code identifier in the DEX Registry.

MammaPrint® was prospectively validated as a microarray assay in the 6,693 patient MINDACT trial in early stage breast cancer, <5cm up to 3 positive lymph nodes and independent of receptor status. The Mammaprint® NGS test has demonstrated technically equivalent performance to the predicate microarray test.

To bill for MammaPrint® services, submit the following claim information:

- Enter "1" in the Days/Unit field
- For CPT® non-NOC codes, Labs may either use the SV101-7 or SV202-7 (preferred) or the NTE field to submit this required information. For dates of service on or after 01/01/2022, use CPT® code 81523 for the test if

performed by NGS.

- Enter the DEX Z-Code[™] identifier adjacent to the CPT[®] code in the comment/narrative field for the following Part B claim field/types:
 - Loop 2400 or SV101-7 for the 5010A1 837P
 - Item 19 for paper claim
- Enter the appropriate DEX Z-Code[™] identifier adjacent to the CPT[®] code in the comment/narrative field for the following Part A claim field/types:
 - Line SV202-7 for 837I electronic claim
 - Block 80 for the UB04 claim form

Only one test- NGS or microarray may be performed on a given date of service for a given patient.

Note: Noridian expects this test may be performed upon occasion twice per patient lifetime for bilateral disease. Should a patient experience an additional occurrence, coverage may be considered with supporting documentation through the appeal process.

Coding Information

CPT/HCPCS Codes			
Group 1 Paragraph:			
N/A			
Group 1 Codes: (3 Codes)	Group 1 Codes: (3 Codes)		
CODE	DESCRIPTION		
81479	Unlisted molecular pathology		
81521	Onc breast mrna 70 genes		
81523	Onc brst mrna 70 cnt 31 gene		

CPT/HCPCS	Modifiers
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Group	1	Paragraph:
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N/A

Group 1 Codes:

N/A

ICD-10-CM Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes: (36 Codes)

Group 1 Codes: (36 Codes)			
CODE	DESCRIPTION		
C50.011	Malignant neoplasm of nipple and areola, right female breast		
C50.012	Malignant neoplasm of nipple and areola, left female breast		
C50.021	Malignant neoplasm of nipple and areola, right male breast		
C50.022	Malignant neoplasm of nipple and areola, left male breast		
C50.111	Malignant neoplasm of central portion of right female breast		
C50.112	Malignant neoplasm of central portion of left female breast		
C50.121	Malignant neoplasm of central portion of right male breast		
C50.122	Malignant neoplasm of central portion of left male breast		
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast		
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast		
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast		
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast		
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast		
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast		
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast		
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast		
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast		
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast		
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast		
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast		
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast		
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast		
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast		
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast		
C50.611	Malignant neoplasm of axillary tail of right female breast		
C50.612	Malignant neoplasm of axillary tail of left female breast		
C50.621	Malignant neoplasm of axillary tail of right male breast		
C50.622	Malignant neoplasm of axillary tail of left male breast		
C50.811	Malignant neoplasm of overlapping sites of right female breast		

CODE	DESCRIPTION
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
Z17.0	Estrogen receptor positive status [ER+]
Z17.1	Estrogen receptor negative status [ER-]

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

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

ICD-10-PCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

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 article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article 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 article, 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 article should be assumed to apply equally to all Revenue Codes.

N/A

Other Coding Information

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2022	R8	Updated to indicate this article is an LCD Reference Article.
01/01/2022	R7	Under Article Text deleted the first paragraph. The second paragraph was revised to read, "MammaPrint® is a diagnostic test that analyzes the gene expression profile of FFPE breast cancer tissue samples to assess a patient's risk for distant metastasis" and a new third paragraph was added. The second bullet point was revised to add the verbiage, "For dates of service on or after 01/01/2022, use CPT code 81523 for the test if performed by NGS". A new paragraph was added after verbiage regarding instructions on how to submit claims information. This revision is effective for dates of service on or after 1/1/2022.
10/08/2021	R6	10/08/2021: Under Article Text revised the first sentence to read, "MammaPrint®, a next-generation sequencing (NGS)-based diagnostic test that uses gene expression profiling to analyze the gene activity of the identified tumor, has been assigned a unique identifier" and revised the third sentence to read, "MammaPrint® was prospectively validated as a microarray assay in the 6,693 patient MINDACT trial in early stage breast cancer, <5cm up to 3 positive lymph nodes and independent of receptor status. The Mammaprint® NGS test has demonstrated technically equivalent performance to the predicate microarray test".

REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	
	Under CPT/HCPCS Codes Group 1: Codes added 81479. Mammaprint® was inserted throughout the article where applicable.	
	10/01/2015: Under Does the CPT 30% Coding Rule Apply: changed to yes. Retroactive back to the creation of the policy.	
R5	As required by CR 10901 article is converted to a formal billing and coding type article. There is no change in coverage.	
R4	Added the following: "MammaPrint [™] is a qualitative in vitro diagnostic test service, performed in a single laboratory, using the gene expression profile of FFPE breast cancer tissue samples to assess a patients' risk for distant metastasis.	
	MammaPrint was prospectively validated in the 6,693 patient MINDACT trial in early stage breast cancer, <5cm up to 3 positive lymph nodes and independent of receptor status."	
R3	Removed the FDA decision summary.	
R2	Added the FDA decision summary providing the intended use information.	
R1	The following updates were made per the 2018 annual HCPCS update:	
	Added: 81521	
	Deleted: 81479, 84999	
	Added Part A billing instructions.	
	Article number A54446 for Jurisdiction F Part A (JFA) was retired on 01/01/2018 and combined into Jurisdiction F Part B (JFB) article number A54447. JFA and JFB contract numbers will have the same final MCD article number. Coverage remains the same.	
	HISTORY NUMBER R5 R4 R3 R2	

Associated Documents

Related Local Coverage Documents

LCDs

L36256 - MolDX: Molecular Diagnostic Tests (MDT)

Related National Coverage Documents

N/A

Statutory Requirements URLs

N/A

Rules and Regulations URLs

N/A

CMS Manual Explanations URLs

N/A

Other URLs

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS	
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.			
11/22/2023	01/01/2022 - N/A	Currently in Effect (This Version)	
01/25/2022	01/01/2022 - N/A	Superseded	

Keywords

N/A