

LCD Reference Article	Billing and Coding Article
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# Article - Billing and Coding: MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (A58724)

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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**  
A58724

**AMA CPT / ADA CDT / AHA NUBC Copyright Statement**

## Article Title

Billing and Coding: MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer

## Article Type

Billing and Coding

## Original Effective Date

08/08/2022

## Revision Effective Date

03/21/2024

## Revision Ending Date

N/A

## Retirement Date

N/A

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## CMS National Coverage Policy

Title XVIII of the Social Security Act, §1833(e) Prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

CMS Internet-Only Manual, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, §80.1.2 A/B MAC (B) Contacts with Independent Clinical Laboratories

## Article Guidance

### Article Text

The information in this article contains billing, coding or other guidelines that complement the Local Coverage Determination (LCD) for MoIDX: Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer L39007 .

To report a Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer service, please submit the following claim information:

- Select the appropriate CPT® code
- Enter 1 unit of service (UOS)

- Enter the appropriate 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
- Select the appropriate ICD-10-CM code

NOTE: When entering the DEX Z-Code® on the SV101-7 documentation field for Part B claims please do not add additional characters and/or information on the line.

Additional information:

- Only one molecular biomarker test may be performed per date of service.
- Only one molecular biomarker test may be performed for a given clinical indication, as allowed by the policy.

## Coding Information

### CPT/HCPCS Codes

#### Group 1 Paragraph:

The following tests may be billed in the post-biopsy setting (after a negative or non-malignant biopsy, as defined in the policy) for individuals contemplating a repeat biopsy:

- ProgenSA PCA3 assay (CPT 81313), performed on post-digital rectal exam (DRE) urine specimens
- ConfirmMDx assay (CPT 81551), performed on formalin-fixed, paraffin embedded (FFPE) tissue specimens.

#### Group 1 Codes: (4 Codes)

CODE	DESCRIPTION
81313	PCA3/KLK3 (PROSTATE CANCER ANTIGEN 3 [NON-PROTEIN CODING]/KALLIKREIN-RELATED PEPTIDASE 3 [PROSTATE SPECIFIC ANTIGEN]) RATIO (EG, PROSTATE CANCER)
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE
81551	ONCOLOGY (PROSTATE), PROMOTER METHYLATION PROFILING BY REAL-TIME PCR OF 3 GENES (GSTP1, APC, RASSF1), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS A LIKELIHOOD OF PROSTATE CANCER DETECTION ON REPEAT BIOPSY
0005U	ONCOLOGY (PROSTATE) GENE EXPRESSION PROFILE BY REAL-TIME RT-PCR OF 3 GENES (ERG, PCA3, AND SPDEF), URINE, ALGORITHM REPORTED AS RISK SCORE

#### Group 2 Paragraph:

The following test may be billed in the pre-biopsy setting as defined in the policy:

SelectMDx assay (PLA 0339U), performed on post-digital rectal exam (DRE) urine specimens.

**Group 2 Codes:** (2 Codes)

CODE	DESCRIPTION
0005U	ONCOLOGY (PROSTATE) GENE EXPRESSION PROFILE BY REAL-TIME RT-PCR OF 3 GENES (ERG, PCA3, AND SPDEF), URINE, ALGORITHM REPORTED AS RISK SCORE
0339U	ONCOLOGY (PROSTATE), MRNA EXPRESSION PROFILING OF HOXC6 AND DLX1, REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR), FIRST-VOID URINE FOLLOWING DIGITAL RECTAL EXAMINATION, ALGORITHM REPORTED AS PROBABILITY OF HIGH-GRADE CANCER

**CPT/HCPCS Modifiers**

**Group 1 Paragraph:**

N/A

**Group 1 Codes:**

N/A

**ICD-10-CM Codes that Support Medical Necessity**

**Group 1 Paragraph:**

The following codes are covered

**Group 1 Codes:** (5 Codes)

CODE	DESCRIPTION
D29.1	Benign neoplasm of prostate
D40.0	Neoplasm of uncertain behavior of prostate
N40.2	Nodular prostate without lower urinary tract symptoms
N40.3	Nodular prostate with lower urinary tract symptoms
R97.20	Elevated prostate specific antigen [PSA]

**Group 2 Paragraph:**

The following codes are covered

**Group 2 Codes:** (5 Codes)

CODE	DESCRIPTION
D29.1	Benign neoplasm of prostate
D40.0	Neoplasm of uncertain behavior of prostate
N40.2	Nodular prostate without lower urinary tract symptoms
N40.3	Nodular prostate with lower urinary tract symptoms
R97.20	Elevated prostate specific antigen [PSA]

**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
03/21/2024	R3	Under <b>CPT/HCPCS Codes Group 1: Codes</b> added 0005U. Under <b>CPT/HCPCS Codes Group 2: Codes</b> added 0005U. This revision is due to new covered assay that has successfully completed a TA and is effective 12/27/2023.
11/02/2023	R2	Updated to indicate this article is an LCD Reference Article.
11/02/2023	R1	<p>Under <b>Article Text</b> revised the 3<sup>rd</sup> and 6<sup>th</sup> bullets to remove "DEX Z-Code™" and replaced with "DEX Z-Code®". Added "<b>NOTE:</b> When entering the DEX Z-Code® on the SV101-7 documentation field for Part B claims please do not add additional characters and/or information on the line". Under subheading <b>Additional information</b> deleted third sentence and Table 1. This revision is effective 11/2/2023.</p> <p><b>Under CPT/HPCS Codes Group 2: Paragraph</b> added "The following test may be billed in the pre-biopsy setting as defined in the policy: SelectMDx assay (PLA 0339U), performed on post-digital rectal exam (DRE) urine specimens". Under <b>CPT/HCPCS Codes Group 2: Codes</b> added 0339U. Under <b>ICD-10 Codes that Support Medical Necessity Group 2: Paragraph</b> added "The following codes are covered". Under <b>ICD-10 Codes that Support Medical Necessity Group 2: Codes</b> added D29.1, D40.0, N40.2, N40.3, and R97.20. The revision is due to new covered assay that has successfully completed a TA and is effective 2/17/2023.</p> <p>Under <b>Article Text</b> removed the sentence: Medical record documentation must indicate the rationale for performance of such diagnostic biomarker tests as Noridian has modified certain language in the articles to mirror the language used presently by the MoIDX team at Palmetto GBA as part of an annual review. Revision history dates</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		and language may not exactly match the MoIDX PGBA revision history. However, these revisions do not change coverage or guidance.

## Associated Documents

### Related Local Coverage Documents

#### LCDs

[L39007 - MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer](#)

### 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
03/12/2024	03/21/2024 - N/A	Currently in Effect (This Version)
11/22/2023	11/02/2023 - 03/20/2024	Superseded
10/27/2023	11/02/2023 - N/A	Superseded
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## Keywords

N/A