Local Coverage Article:
Billing and Coding: MolDX: Progensa® PCA3 Assay (A54489)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

## Contractor Information

<table>
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<tr>
<th>CONTRACTOR NAME</th>
<th>CONTRACT TYPE</th>
<th>CONTRACT NUMBER</th>
<th>JURISDICTION</th>
<th>STATE(S)</th>
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<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>01111 - MAC A</td>
<td>J - E</td>
<td>California - Entire State</td>
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<td>J - E</td>
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Article Information

General Information

Article ID
A54489

Article Title
Billing and Coding: MolDX: Progensa® PCA3 Assay

Article Type
Billing and Coding

AMA CPT / ADA CDT / AHA NUBC Copyright Statement
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Original Effective Date
10/01/2015

Revision Effective Date
11/01/2019

Revision Ending Date
N/A

Retirement Date
N/A
CMS National Coverage Policy

N/A

Article Guidance

Article Text:

The following coding and billing guidance is to be used with its associated Local coverage determination.

Progensa® PCA3 Assay, an FDA approved test by Gen-Probe Incorporated, is an mRNA expression assay used alone or in combination with other molecular tests for prostate cancer determination to identify patients with increased risk of prostate cancer. PCA3 may help to improve the specificity of prostate cancer detection providing additional information about the risk of prostate cancer over the use of the PSA test alone. Based on the ratio of PCA3 mRNA/PSA mRNA x1000, the PCA3 assay is performed on the first urine collected following an attentive digital rectal examination.

PCA3 testing is covered **ONLY** when all biopsies in previous encounter(s) are negative and when the patient or physician wants to avoid repeat biopsy (watchful waiting).

When the physician plans to biopsy the prostate, the CMS MolDX contractor will consider a PCA3 test as investigational and thus, not a covered Medicare benefit. The CMS MolDX contractor considers all other indications for PCA3 not reasonable and necessary.

Medical record documentation must indicate the rationale to perform a PCA3 assay. Providers who report a PCA3 service AND perform a biopsy may be referred for additional action.

To report a PCA3 service, submit the following claim information:

- 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:** Effective 10/15/2012, Noridian will deny all laboratory developed tests (LDT) for PCA3 as statutorily excluded services that do not support the required clinical utility for the established Medicare benefit category. Only the unmodified FDA approved test will be reimbursed.
**CPT/HCPCS Codes**

**Group 1 Paragraph:**
N/A

**Group 1 Codes:**

<table>
<thead>
<tr>
<th>CODE</th>
<th>DESCRIPTION</th>
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<tr>
<td>81313</td>
<td>PCA3/KLK3 (PROSTATE CANCER ANTIGEN 3 [NON-PROTEIN CODING]/KALLIKREIN-RELATED PEPTIDASE 3 [PROSTATE SPECIFIC ANTIGEN]) RATIO (EG, PROSTATE CANCER)</td>
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**CPT/HCPCS Modifiers**

N/A

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

**Group 1 Paragraph:**
N/A

**Group 1 Codes:**

<table>
<thead>
<tr>
<th>ICD-10 CODE</th>
<th>DESCRIPTION</th>
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<tr>
<td>D29.1</td>
<td>Benign neoplasm of prostate</td>
</tr>
<tr>
<td>D40.0</td>
<td>Neoplasm of uncertain behavior of prostate</td>
</tr>
<tr>
<td>N40.0</td>
<td>Benign prostatic hyperplasia without lower urinary tract symptoms</td>
</tr>
<tr>
<td>N40.2</td>
<td>Nodular prostate without lower urinary tract symptoms</td>
</tr>
<tr>
<td>N40.3</td>
<td>Nodular prostate with lower urinary tract symptoms</td>
</tr>
<tr>
<td>N41.0</td>
<td>Acute prostatitis</td>
</tr>
<tr>
<td>N42.9</td>
<td>Disorder of prostate, unspecified</td>
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<tr>
<td>R31.1</td>
<td>Benign essential microscopic hematuria</td>
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<tr>
<td>R31.21</td>
<td>Asymptomatic microscopic hematuria</td>
</tr>
<tr>
<td>R31.29</td>
<td>Other microscopic hematuria</td>
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<tr>
<td>R35.1</td>
<td>Nocturia</td>
</tr>
<tr>
<td>R39.12</td>
<td>Poor urinary stream</td>
</tr>
<tr>
<td>R39.14</td>
<td>Feeling of incomplete bladder emptying</td>
</tr>
<tr>
<td>R97.20</td>
<td>Elevated prostate specific antigen [PSA]</td>
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**ICD-10 Codes that DO NOT Support Medical Necessity**

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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

Revision History Information

<table>
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<tr>
<th>REVISION HISTORY DATE</th>
<th>REVISION HISTORY NUMBER</th>
<th>REVISION HISTORY EXPLANATION</th>
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<tr>
<td>11/01/2019</td>
<td>R3</td>
<td>As required by CR 10901 article is converted to a formal billing and coding type article. There is no change in coverage.</td>
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<tr>
<td>10/01/2016</td>
<td>R2</td>
<td>The following revisions were made due to annual ICD-10 updates effective 10/1/16: R31.21, R31.29 and R97.20 were added and R31.2 and R97.2 were deleted. The Part A article (A54487) is retired and Part A contract numbers are added to the Part B article. Z-Code Identifier references were replaced with unique identifier.</td>
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</table>
10/01/2015 | R1 | Article is revised to replace CPT 81479 with 81313 effective for dates of service on/after 10/1/15. The following verbiage was added to the Note: Only the unmodified FDA approved test will be reimbursed.

Associated Documents

Related Local Coverage Document(s)
LCD(s)
L35160 - MolDX: Molecular Diagnostic Tests (MDT)

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)
Updated on 10/16/2019 with effective dates 11/01/2019 - N/A
Updated on 09/27/2016 with effective dates 10/01/2016 - N/A
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords
N/A