Local Coverage Article:
MolDX: Progensa® PCA3 Assay Coverage Update (A53107)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Palmetto GBA	A and B MAC	10111 - MAC A	J - J	Alabama
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10211 - MAC A	J - J	Georgia
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10311 - MAC A	J - J	Tennessee
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11201 - MAC A	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11301 - MAC A	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11401 - MAC A	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11501 - MAC A	J - M	North Carolina
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

Article Information

General Information

Article ID
A53107

Original Effective Date
10/01/2015

Original ICD-9 Article ID
A51964

Revision Effective Date
02/26/2018

Article Title
MolDX: Progensa® PCA3 Assay Coverage Update

Revision Ending Date
N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement
CPT codes, descriptions and other data only are

Retirement Date
N/A

Article Guidance

Article Text:

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, MolDX will consider a PCA3 test as investigational and thus, not a covered Medicare benefit. MolDX 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 CPT code 81313 - PCA3/KLK3
- 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.
    - 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
        - Box 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 diagnosis

NOTE: Effective 10/15/2012, MolDX 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

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Coding Information

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

CPT/HCPCS Codes

N/A

ICD-10 Codes that are Covered

Group 1 Paragraph:

N/A

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
D29.1	Benign neoplasm of prostate
D40.0	Neoplasm of uncertain behavior of prostate
N40.0	Benign prostatic hyperplasia without lower urinary tract symptoms
N40.2	Nodular prostate without lower urinary tract symptoms
N40.3	Nodular prostate with lower urinary tract symptoms
N41.0	Acute prostatitis
N42.9	Disorder of prostate, unspecified
R31.1	Benign essential microscopic hematuria
R31.21	Asymptomatic microscopic hematuria
R31.29	Other microscopic hematuria
R35.1	Nocturia
R39.12	Poor urinary stream
R39.14	Feeling of incomplete bladder emptying
R97.20	Elevated prostate specific antigen [PSA]

ICD-10 Codes that are Not Covered

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
02/26/2018	R11	The Jurisdiction "J" Part B Contracts for Alabama (10112), Georgia (10212) and Tennessee (10312) are now being serviced by Palmetto GBA. The notice period for this article begins on 12/14/17 and ends on 02/25/18. Effective 02/26/18, these three contract numbers are being added to this article. No coverage, coding or other substantive changes (beyond the addition of the 3 Part B contract numbers) have been completed in this revision.
01/29/2018	R10	The Jurisdiction "J" Part A Contracts for Alabama (10111), Georgia (10211) and Tennessee (10311) are now being serviced by Palmetto GBA. The notice period for

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		this article begins on 12/14/17 and ends on 01/28/18. Effective 01/29/18, these three contract numbers are being added to this article. No coverage, coding or other substantive changes (beyond the addition of the 3 Part A contract numbers) have been completed in this revision.
04/27/2017	R9	Annual review completed. Updated Part-A & Part B billing instructions.
10/01/2016	R8	ICD-10 codes update: Deleted R31.2 and R97.2; Added R31.21, R31.29, and R97.20
10/01/2015	R7	Added the word "assigned" before Z-Code Identifier
10/01/2015	R6	Removed 84999 and 84179. Added 81313.
10/01/2015	R5	Removed Z-Code ID reference.
10/01/2015	R4	Removed Z-Code ID.
10/01/2015	R3	Removed ICD-9 and ICD-10 codes from article text and added ICD-10 codes to the ICD-10 code section.
10/01/2015	R2	Added Annual Review Date.
10/01/2015	R1	Updated Clinical Utility verbiage. Removed Investigational language.

Associated Documents

Related Local Coverage Document(s)

LCD(s)
L35025 - 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 12/14/2017 with effective dates 02/26/2018 - N/A
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A