

Subject: Genetic Testing for Prostate Cancer

Medical Policy #: 7.8

Status: Reviewed

Original Effective Date: 09/25/2019

Last Review Date: 07/26/2023

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

This Medical Policy includes information on the following items:

Diagnostic Testing:

- I. Progenesa® PCA3 Assay (CPT code 81313):
- II. BRCA1 and BRCA2 Genetic Testing for Prostate Testing:
- III. ConfirmMDx Epigenetic Molecular Assay (CPT code 81551):
- IV. ExoDx Prostate (EPI), formerly known as ExosomeDx Prostate Test,
- V. SelectMDX (CPT code 81479)
- VI. Myprostatescore (MPS) (CPT code 0113U)

Treatment/Management Testing:

- I. Prostate Cancer Genomic Classifier Assay for Men with Localized Disease Test:
- II. ProMark Risk Score:
- III. Androgen Receptor Variant (AR-V7) Protein Test

Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: <https://ds.phs.org/preslogin/index.jsp>

Diagnostic Testing:

- I. **Progenesa® PCA3 Assay (CPT code 81313):**
For Medicare, Medicaid and Commercial members:
PHP follows WPS, MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer, [L39042](#) related LCA ([A58759](#)).
 - Initial biopsy decision making (first-line screening test) is **not** a covered benefit.
 - Post-biopsy setting is a covered benefit.
- II. **BRCA1 and BRCA2 Genetic Testing for Prostate Testing:**
For Medicaid and Commercial members:
PHP follows the current version NCCN guidelines.

For Medicare members:
PHP follows BRCA1 and BRCA2 Genetic Testing by Novitas LCD ([L36715](#)), with related Article LCA ([A56542](#)).
- III. **ConfirmMDx Epigenetic Molecular Assay (CPT code 81551):**
For Medicare, Medicaid and Commercial members:
PHP follows WPS, MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer, [L39042](#), related LCA ([A58759](#)).
 - Initial biopsy decision making (first-line screening test) is **not** a covered benefit.
 - Post-biopsy setting is a covered benefit.
- IV. **ExoDx Prostate** (EPI), formerly known as ExosomeDx Prostate Test, (CPT code 0005U)
For Medicare, Medicaid and Commercial members:
PHP follows WPS, MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer, [L39042 and related](#) LCA ([A58759](#)).

V. **SelectMDX (CPT code 81479)**

For Medicare, Medicaid and Commercial members:

PHP follows WPS, MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer, [L39042 and related LCA \(A58759\)](#).

VI. **Myprostatescore (MPS) (CPT code 0113U)**

For Medicare, Medicaid and Commercial:

PHP follows Novitas, CMS Genetic Testing for Oncology, LCD ([L39365](#)), LCA ([A59125](#)). For criteria see LCA ([A59125](#)).

Treatment/Management Testing:

I. **Prostate Cancer Genomic Classifier Assay for Men with Localized Disease Test:**

For Medicaid and Commercial members:

PHP follows NCCN guidelines for Decipher, Oncotype DX Prostate, and Prolaris.:

For Medicare members:

PHP follows CMS WPS, MoIDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease ([L38433](#)) with related Policy Article Prostate Cancer Genomic Classifier Assay for Men with Localized Disease ([A57106](#)) is covered only when the following conditions are met:

Note: The following previous tests have been consolidated to LCD (L38433): **Decipher®** Prostate Cancer Classifier Assay Test (for radical prostatectomy (RP)); Decipher® Biopsy Prostate Cancer Classifier Assay for Men with Very Low and Low Risk Disease; Decipher® Biopsy Prostate Cancer Classifier Assay for Men with Intermediate Risk Disease; Genomic Health™ **Oncotype DX®** Prostate Cancer Assay; Oncotype DX® Genomic Prostate Score for Men with Favorable Intermediate Risk Prostate Cancer; **Prolaris™** Prostate Cancer Genomic Assay; and Prolaris™ Prostate Cancer Genomic Assay for Men with Favorable Intermediate Risk Disease.

This is a limited coverage policy for Genomic derived tests that assess risk in localized (non-metastatic) prostate cancer. The review is focused on the Decipher® Prostate Cancer Classifier Assay (identified as Decipher® to follow). The test is considered reasonable and necessary to help identify men with localized Prostate Cancer and a life expectancy of at least 10 years who are good candidates for active surveillance according to the most recent National Comprehensive Cancer Network (NCCN) guidelines.

II. **ProMark Risk Score:**

Not a covered benefit for Medicaid and Commercial members.

For Medicare members only:

For purpose of criteria PHP follows CMS, WPS ProMark Risk Score, LCD ([L37011](#)) with related Policy Article ([A57587](#)). The test help to determine which patients with early stage, needle biopsy proven prostate cancer can be conservatively managed rather than treated with definitive surgery or radiation therapy.

III. **Androgen Receptor Variant (AR-V7) Protein Test**

For Medicare, Medicaid and Commercial:

PHP follows NCCN guidelines on the use of AR-V7 tests which can be considered to help guide selection of therapy in the post-abiraterone/enzalutamide metastatic CRPC setting.

NON-Covered Tests:

For Treatment/Management:

- DeCODE Prostate Cancer™ (for assessment of prostate cancer risk or prostate cancer aggressiveness).

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

Name of Test	CPT Codes	Test Description of Covered Prostate Cancer Test	
Progenesa® PCA3	81313	Progenesa® PCA3 Assay	
BRCA1 & BRCA2	See below table	BRCA1 & BRCA2	
ConfirmMDx	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. For ConfirmMDx Epigenetic molecular Assay.	
ExoDx™ Prostate (EPI)	0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score	
SelectMDX	81479	Unlisted molecular pathology procedure	
Myprostatescore (MPS)	0113U	Oncology (prostate), measurement of PCA3 and TMPRSS2-ERG in urine and PSA in serum following prostatic massage, by RNA amplification and fluorescence-based detection, algorithm reported as risk score	
ProMark	81479	Unlisted molecular pathology procedure	
Androgen Receptor Variant (AR-V7) Protein Test	81479	Unlisted molecular pathology procedure	

CPT Codes	(Progenesa PCA3) test, WPS LCD L39042 and LCA (A58759),
81313	PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 3 [prostate specific antigen]) ratio (e.g., prostate cancer)
ICD-10 Code	ICD-10 diagnosis for Progenesa® PCA3
<p>Refer to the ICD-10 code list in the LCD related Policy Article for applicable diagnosis.</p> <ul style="list-style-type: none"> WPS, MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer, LCA (A58759) 	

CPT CODES	CPT codes applicable to BRCA1 and BRCA2 Genetic Testing see ICD-10 listing in LCA (A56542) and LCA (A55224) for test named BRACAnalysis CDx™
81162	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81165	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81166	BRCA1 (BRCA1, DNA repair associated) (EG, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)

Not every Presbyterian health plan contains the same benefits. Please refer to the member's specific benefit plan and Schedule of Benefits to determine coverage

CPT CODEs	CPT codes applicable to BRCA1 and BRCA2 Genetic Testing see ICD-10 listing in LCA (A56542) and LCA (A55224) for test named BRACAnalysis CDx™
81167	BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81212	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; 185DELAG, 5385INSC, 6174DELT variants
81215	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant
81216	BRCA2 (BRCA2, DNA repair associated) (EG, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81217	BRCA2 (BRCA2, DNA repair associated) (EG, hereditary breast and ovarian cancer) gene analysis; known familial variant
81432	Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 10 genes, always including BRCA1, BRCA2, CDH1, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, AND TP53
81433	Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11
81479	Unlisted molecular pathology procedure
ICD-10 Code	<p>Refer to the ICD-10 code list in the LCD related Policy Article for applicable diagnosis for BRCA1 and BRCA2 Genetic Testing.</p> <ul style="list-style-type: none"> For BRCA1 and BRCA2 Genetic Testing LCD (L36715), see (A56542) for covered diagnosis. For “Myriad’s BRACAnalysis CDx®” see (A55224) for covered diagnoses.

ICD-10 CODE	Covered diagnosis for ConfirmMDX test for CPT 81551
	Refer to the ICD-10 code list in the LCD related Policy Article for applicable diagnosis. MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer, (L39042) related LCA (A58759).

ICD-10 CODE	Covered diagnosis for ExoDx Prostate (EPI) test for CPT 0005U
	See WPS, MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer, (L39042) related LCA (A58759).

ICD-10 CODE	Covered diagnosis for SelectMDX (Code 81479)
	See WPS, MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer. LCD L39042 related LCA (A58759),

ICD-10 CODE	Covered diagnosis for Myprostatescore (MPS) (Code 0113U)
	See Novitas, CMS Genetic Testing for Oncology, LCD (L39365), LCA (A59125).

CPT	Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (L38433)
81541	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a disease-specific mortality risk score
81542	Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score
0047U	Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score
ICD- 10 CM	Covered diagnosis for Prostate Cancer Genomic Classifier Assay for Men with Localized Disease
Refer to the ICD-10 code list in the LCD related Policy Article for applicable diagnosis. For MoIDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease, LCA (A57106) for covered diagnosis.	

ICD- 10 CM	Covered diagnosis for ProMark Risk Score, CPT 81479- (LCD-L37011/A57587) covered diagnosis
Refer to the ICD-10 code list in the LCD related Policy Article for applicable diagnosis. For ProMark Risk Score LCD (L37011), see (A57587) for covered diagnosis.	

Reviewed by / Approval Signatures

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Date Approved: 07/26/2023

References

1. CMS, Local Coverage Determination, 4Kscore Test Algorithm, Original effective date: 03/21/2019, Revision history date: 12/30/2019, R#2, (LCD-L37792), Related Article A56653, revision date: 12/30/2019, R#1 [Cited 06/19/2023]
2. CMS, Local Coverage Determination, Biomarkers for Oncology (for Progenesa) (L35396), Revision date 12/13/2020, R#32. [Cited 06/19/2023]
3. CMS, Billing and Coding Biomarkers for Oncology (A52986), Revision History date: 01/01/2023, R#39. [Cited 06/23/2023].
4. CMS, Novitas Solutions, Inc, Local Coverage Determination BRCA1 and BRCA2 Genetic Testing (L36715). Revision History 12/10/2020, R#6 and related Billing and Coding Article (A56542), Effective date 10/01/2021, R3. [Cited 06/19/2023]
5. CMS Wisconsin Physicians Service Ins. Corp, MoIDX: Myriad's BRCA Analysis CDx Coding and Billing Guidelines (L39040), revision date: 07/03/2022, R1; related LCA (A55224). Revision History date 07/28/2022, R#14. [Cited 06/23/2022]
6. CMS, Wisconsin Physician Service Ins. Corp. MoIDX: Androgen Receptor Variant (AR-V7) Protein Test, (L37915), (Retired) Revision date: 07/24/2021, R3. Related Article (A57102) (Retired), 07/24/2022, R1 [Cited 07/01/2022].
7. CMS, WPS- LCD L38433 MoIDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease, revision 01/27/2022, R1, related LCA A57106, revision date 01/27/2022, R3 [Cited 06/21/2023]
8. CMS, Wisconsin Phys. Serv. Ins. Corp., MoIDX Prolaris™ Prostate Cancer Genomic Assay for Men with Favorable Intermediate Risk Disease, (L37226), 10/28/2021, R#4, incorporated into LCD L38433; Related Article (A57586), revised 10/28/2021 R1, Retired. (see A57106) [Cited 06-21-2023]
9. CMS, Wisconsin Phys. Serv. Ins. Corp., Local coverage Determination, ProMark Risk Score, LCD (L37011), Revision Date 02/24/2022, R#8. Related Article (A57587), Effective 11/01/2019, revised 07/28/2022 R2 [Cited 06-21-2023].
10. CMS, Proposed Local Coverage Determination (LCD): MoIDX: Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39042), effective date 07/03/2022, related LCA (A58759), effective 05/10/2022. [Cited 06/19/2023]
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23. Aetna, Tumor Marker, [Number: 0352](#), Next review 03/21/2024. [Cited 06/219/2023]
24. Cigna, Molecular Diagnostic Testing for Hematology and Oncology Indications, Effective Date: 04/01/2022, Next review: 02/15/2024, Policy Number [0520](#). [Cited 06/19/2023]
25. Humana, Laboratory Analysis for Prostate Cancer, Policy Number: HUM-0594-005, Review Date: 07/27/2022 Effective date: 03/23/2023. [Cited 06/19/2023]
26. Humana, Gene Expression Profiling for Prostate Cancer, Policy Number: HUM-0602-002, Effective Date: 08/25/2022, Review Date: 08/25/2022. [Cited 06/19/2023]
27. UHC, Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions, Policy Number: 2023T0588Z, Effective Date: April 1, 2023 [Cited 06/19/2023]

Publication History

- 09-25-19: MPM policy follows CMS guidelines. Reviewed Hayes for all tests.
- 05-08-20: Error: Correction of MPM number, from 7.7 to 7.8.
- 07-22-20: Update policy to add Decipher® Biopsy and 4Kscore for Medicare coverage only. Reviewed by PHP Medical Policy Committee on July 08, 2020. Add 4Kscore (CPT 81539). Replaced 81479 with 81542 for all three Decipher testing. Additional new codes added for BRCA1/2: 0102U, 0103U, 0129U, 0131U, 0132U, 0133U, 0134U, 0135U, 0136U, 0137U, 0138U, 0157U, 0158U, 0159U, 0160U, 0161U, 0162U. All of the mentioned codes above plus these codes will require PA 0047U, 81163, 81164, 81165, 81166, 81167, 0005U, 81539 and 81542. Restructured the policy for easy reading.
- 07-28-21 Annual review. Reviewed by PHP Medical Policy Committee on June 23, 2021. The following were updated.
- For 4kscore: No change in criteria, will continue coverage for Medicare only and continue PA. NCCN does not fully recommend the use of 4Kscore.
 - Prognosis PCA3 Assay: No change in criteria, will continue coverage for Medicare only and continue PA. NCCN does not valid both PCA3 and percent free PSA (%f PSA).
 - For BRCA 1&2: no criteria change to LCD L36813 for Medicare. Added new criteria for BRCAAnalysis CDx (A55224) and LCD L36715/A56542; Continue PA. Will continue to follow NCCN for Commercial and Medicaid. BRCA1/2 LCA (A56542 and A57771) removed CPT codes 81445 and 81455
 - ConfirmMDx Epigenetic: No change in criteria, will continue coverage for Medicare only and continue PA. NCCN does not fully recommend the use of ConfirmMDx for early detection. Change to Decipher and Oncotype: CMS retired the following LCDs: Decipher® Prostate Cancer Classifier Assay (**L36791/A57565**); Decipher® Biopsy Prostate Cancer Classifier Assay for Men w/ for Men with Very Low and Low Risk Disease(**L37911/A57564**); Decipher® Biopsy Prostate Cancer Classifier Assay for Men with Intermediate Risk Disease (**L38166/A57798**); Genomic Health™ Oncotype DX® Prostate Cancer Assay (**L36789** A56334); Oncotype DX® Genomic Prostate Score for Men with Favorable Intermediate Risk Prostate Cancer (**L37667/A56334**); because the information has been incorporated/consolidated to the new LCD L38433/A57106.
- Added new criteria from MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease LCD L38433/A57106. Coverage also extended for Decipher and Oncotype DX for Commercial and Medicaid based on NCCN Prostate Cancer footnote “J” which recommends these tests. Will continue PA.
- Retired criteria for: CMS made changes to LCD MolDX: Oncotype DX AR-V7 Nucleus Detect for Men with Metastatic Castrate Resistant Prostate Cancer (MCRPC) (L37915) now with a new title MolDX: Androgen Receptor Variant (AR-V7) Protein Test (L37915) which has been retired without announcement of replacement as of July 24, 2021. No current DL37915 found.
- Prolaris: For Medicare continue to follow the two LCDs (L36787 & L37226), these LCDs has no criteria change). Coverage benefit now includes Commercial and Medicaid which will follow NCCN Prostate Cancer recommendation as stated in the “j” footnotes. Continue PA.
 - ProMark: No criteria change for ProMark Risk Score, LCD (L37011), will continue coverage for Medicare only. NCCN does not support ProMark. Continue PA.
 - Currently non-covered includes: SelectMDX, DeCode and ExoDX.
- Reference section updated on 12/09/2021: NCCN, Prostate Cancer Version 2.2021 (footnote j on page PROS-2A) and NCCN, Prostate Cancer Version 2.2022. (See “Principles of Risk Stratification” on page PROS-C 1 OF 3.
- 07-27-22 Annual review. Reviewed by PHP Medical Policy Committee on 07/01/2022. The following were updated.
- Diagnostic Testing:**
- 4kscore test: Change. No longer just for Medicare. Extended coverage to Medicaid and Commercial and will follow LCD (L39042) and LCA (A58759), even though there is an LCD L37792 specific to

4kscore. Rationale: The LCD (L39042) lists multiple tests under one policy which includes 4kscore and LCD (L37792) has not been updated since 12/30/2019. NCCN recommends 4kScore under first-line screening test and post biopsy test. Continue PA requirement for code 81539.

- **Progensa PCA3 Assay:** No longer just for Medicare. Extended coverage to Medicaid and commercial and will follow LCD (L39042) and LCA (A58759), even though there are two LCDs (L36807) and (L35396) for Progensa. Rationale: The LCD L37792 lists multiple tests under one policy. NCCN recommends Progensa PCA 3 under post biopsy setting. Continue PA requirement for code 81313, 81321, 81322, 81323 and 81479.
- **For BRCA 1&2:** No change. For Medicare continue to follow two LCDs. WPS, LCD L36813/ LCA A57771 and BRACAnalysis CDx (A55224) and LCD L36715/ LCA A56542. The coverage determination guideline language removed from policy and reformatted to only include Local Coverage Determination (LCD) weblinks. Continue to follow NCCN for Commercial and Medicaid. Continue to require PA for affiliated codes.
- **ConfirmMDx Epigenetic:** Change, no longer just for Medicare. Extended coverage to Medicaid and commercial and will follow LCD L39042 and LCA (A58759). NCCN recommends ConfirmMDx under post biopsy setting. Continue PA for 81551. LCD ConfirmMDx Epigenetic Molecular Assay LCD (L37005), has been retired and advise to use LCD (L39042) and LCA (A58759). The coverage determination guideline language removed from policy and reformatted to only include LCD weblinks.
- **ExoDx Prostate (EPI):** Now covered for all LOB. Previously EPI was listed as non-covered. Will follow LCD (L39042) and LCA (A58759). CPT 0005U will continue to require PA. NCCN recommends EPI for both pre-biopsy and post biopsy testing.
- **SelectMDX:** Now covered for all LOB. Previously SelectMDX was non-covered. Will follow LCD L39042/LCA (A58759). CPT 81479 will continue to require PA. Per draft article (DA56609), use 81479 for SelectMDX.
- **Non-covered test:** According to LCD (L39042) and LCA (A58759) and NCCN these tests are not covered IsoPSA and MyProstateScore (MPS) for both pre-biopsy and post biopsy setting.

Treatment:

- **Prostate Cancer Genomic Classifier Assay for Men with Localized Disease:** continue coverage for Decipher test. Continue to follow LCD (L38433) and (A57106) for Medicare and for Commercial and Medicaid continue to follow NCCN. CPT codes 81541, 81542, 0047U will continue PA. The coverage determination guideline language removed from policy and reformatted to only include LCD weblinks.
- Both Prolaris tests has been moved to the consolidated list of tests under Prostate Cancer Genomic Classifier Assay for Men with Localized Disease. Both LCD (L36787) related LCA (A57585) and LCD (L37226) related (A57586) have been retired and incorporated into LCD (L38433) and LCA (A57106). CPT 81541 will continue PA requirement. All related retired LCDs and LCA were removed from policy and test name (Prolaris) was added to the consolidated list.
- **ProMark Risk Score:** No criteria change. LCD removed "MoIDX" from title for ProMark Risk Score, LCD (L37011), will continue coverage for Medicare only. NCCN does not support ProMark. Continue PA for 81479. The coverage determination guideline language removed from policy and reformatted to only include LCD weblinks.
- **Androgen receptor splice variant 7 (AR-V7):** New test added for Medicare, Medicaid and Commercial, which will follow NCCN. Previous LCD (L37915) retired without further announcement of an LCD that replaced the retired LCD as of July 24, 2021, still no current LCD found. Continue PA for 81479.

07-26-2023

Annual review. Reviewed by PHP Medical Policy Committee on 06/21/2023. The following were updated.

Diagnostic Testing:

- **4kscore:** Removed the 4Kscore test from policy, since it is not a genetic related test. This test is a blood-based biomarker test that is used to determine which patient should proceed the prostate biopsy. PA requirement for 81539 will be removed.
- **Progensa PCA3:** Continue to follow WPS LCD (L39042) and LCA (A58759) for ALOB, since Novitas LCD L35396 lacks criteria. Continue PA requirement for code 81313. Remove from policy codes that are not related specifically to PCA3: 81321, 81322, 81323 and 81479.
- **For BRCA 1/2:** Change. Medicare: will only follow Novitas LCD (L36715), with related Article LCA (A56542). Removed WPS BRCA1/2, LCD (L36813) and related LCA (A57771) as well as WPS MoIDX: Germline testing for use of PARP inhibitors, (which mentions Myriad's BRACAnalysis CDx), LCA (A55224). For Commercial & Medicaid will continue to follow NCCN. Continue to require PA for those codes listed in Novitas LCA (A56542) - 81162, 81163, 81164, 81165, 81166, 81167, 81212, 81215, 81216, 81217, 81432 and 81433. Removed other genetic testing CPT not specifically related to Prostate Test, which includes: 0102U, 0103U, 0129U, 0131U, 0132U, 0133U, 0134U, 0135U, 0136U, 0137U, 0138U, 0157U, 0158U, 0159U, 0160U, 0161U, and 0162U.
- **ConfirmMDx Epigenetic:** Continue to follow LCD (L39042) and LCA (A58759) for ALOB. Continue PA for 81551.
- **ExoDx Prostate (EPI):** Continue to LCD (L39042) and LCA (A58759) for ALOB. Continue to require PA for_0005U.
- **SelectMDX:** Continue to follow LCD L39042/LCA (A58759) for ALOB. CPT 81479 will continue to require PA.
- **IsoPSA:** Removed the test from the policy. Remove PA requirement for 0359U for ALOB since this is a laboratory diagnostic code and not a genetic code. BCG group to un-classify code 0359U as genetic

test and classify as lab test for ALOB.

- **Myprostatescore (MPS):** Change. Previously non-covered but now a covered test for ALOB. Will follow Novitas LCD L39365 and LCA A59125. The PLA code 0113U will be config to require PA for ALOB.

Treatment:

- **Prostate Cancer Genomic Classifier Assay for Men with Localized Disease:** No change. For Medicare continue to follow LCD L38433/LCA A57106 for which Decipher, Oncotype DX, and Prolaris has been consolidated. For Commercial and Medicaid continue to follow NCCN. CPT codes 81541, 81542, 0047U will continue PA.
- **ProMark Risk Score:** No change. Coverage for Medicare only, which will continue to follow LCD (L37011), NCCN is silent and EviCore deems ProMark investigational. Continue PA for 81479.
- **Androgen receptor splice variant 7 (AR-V7):** Continue to follow NCCN for Medicare, Medicaid and Commercial. No specific LCD. Continue PA for 81479.
- **deCODE ProstateCancer:** no change. Continue as non-covered test for ALOB.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: [Click here for Medical Policies](#)

Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.