

Subject: Genetic Testing for Prostate Cancer

Medical Policy #: 7.8

Status: Reviewed

Original Effective Date: 09/25/2019

Last Review Date: 08/21/2024

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 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 (See Table of Coding for CPT Reference):**
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 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) (CPT 0005U), 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 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](#)).

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 (CPT 81542), Oncotype DX Prostate (CPT 0047U), and Prolaris (CPT 81541).

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](#)), for specific coverage when the 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 (CPT 81479):**

Not a covered benefit for Medicaid and Commercial members per NCCN guidelines. Decipher is an equivalent test with coverage (listed above).

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 CPT 81479)**

For Medicare Medicaid and Commercial:

For purpose of criteria PHP follows CMS, WPS MoIDX: Phenotypic Biomarker Detection from Circulating Tumor Cells, LCD ([L38678](#)) with related Policy Article ([A58205](#)).

NON-Covered Tests for all lines of business:

Diagnostic

- [Myprostatescore \(MPS\) \(CPT 0113U\)](#)

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 |

| ICD-10 Code | ICD-10 diagnosis for Genetic Testing for Prostate Cancer Diagnoses and Treatment |
|---|--|
| Refer to the ICD-10 code list in the LCD related Policy Article (LCA) for applicable diagnoses on the covered services, as indicated in the criteria section of this policy. | |

| CPT CODEs | Table of CPT codes applicable to BRCA1 and BRCA2 Genetic Testing |
|-----------|---|
| 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) |
| 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 |

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| CPT CODEs | Table of CPT codes applicable to BRCA1 and BRCA2 Genetic Testing |
|-----------|---|
| 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 |

Reviewed by / Approval Signatures

Clinical Quality & Utilization Mgmt. Committee: Clinton White, MD

Senior Medical Director: Jim Romero, MD

Date Approved: 08/21/2024

References

1. CMS, Local Coverage Determination, 4Kscore Test Algorithm, Original effective date: 03/21/2019, Revision date: 12/30/2019, R2, (L37792), Related Article (A58759), revision date: 12/30/2019 [Cited 07/31/2024]
2. CMS, Local Coverage Determination, Molecular Biomarkers to Risk-Stratify (Used for PCA3, ExoDx (EPI) and SelectMDx) (L39042), Revision date 7/27/2023, R1, Related Article (A58759) [Cited 07/25/2024]
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 date 12/10/2020, R6 and related Billing and Coding Article (A56542), Effective date 10/01/2021, R3. [Cited 07/25/2024]
5. CMS, WPS- LCD L38433 MoIDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease, Revision Date 02/01/2024, R2, related LCA A57106, Revision Date 02/01/2024, R4 [Cited 08/06/2024]
6. CMS, Prostate CA Genomic Classifier Assay for Men w/ Localized Disease LCD (L38433) R2; Related Article (A57106), revised 02/01/2024 R4, [Cited 08/06/2024]
7. CMS, Wisconsin Phys. Serv. Ins. Corp., Local coverage Determination, ProMark Risk Score, LCD (L37011), Revision Date 12/28/2023, R9. Related Article (A57587), Revision Date 12/28/2023 R3 [Cited 08/07/2024].
8. CMS, MoIDX: Phenotypic Biomarker Detection from Circulating Tumor Cells: Androgen Receptor Variant (AR-V7) Protein Test, (38678), Revision date: 05/26/2022, R2. Related Article (A58205), 05/26/2022, R4 [Cited 08/07/2024].
9. NCCN Guidelines Version 4.2024 3/6/2024 Prostate Cancer Early Detection [Cited 08/07/2024]
10. NCCN, Guidelines Version 4 2024 Prostate Cancer, [Cited 08/07/2024]
11. Hayes, PCA3 Detection Test for Prostate Cancer, Revised 5/14/2015. [Cited 08/01/2024].
12. Hayes, Decipher Prostate Biopsy (Decipher Biosciences) Molecular Test Assessment, May 21, 2019, Annual Review: Mar 21, 2022 [Cited 08/07/2024]
13. Hayes, Decipher Prostate RP (Decipher Biosciences) Molecular Test Assessment May 21, 2019, Annual Review: Mar 21, 2022, [Cited 08/07/2024]
14. Hayes, ProMark Proteomic Prognostic Test, (Metamark Genetics Inc.) Annual Review July 17, 2020, [Cited 08/07/2024]
15. Hayes, SelectMDx for Prostate Cancer (MDxHealth Inc.), Molecular Test Assessment, Mar 21, 2019, revised 05/22/2024, [Cited 08/07/2024]
16. Hayes, Oncotype DX Genomic Prostate Score (GPS) Assay (Genomic Health Inc.), Molecular Test Assessment Nov 12, 2018 Annual Review: Jun 17, 2022, [Cited 08/07/2024]
17. Hayes, Prolaris Biopsy Test (Myriad Genetic Laboratories Inc.), Annual review: Feb 14, 2022, [Cited 08/07/2024]
18. Hayes, Prolaris Post-Prostatectomy (Myriad Genetic Laboratories Inc.), Mol. Assessment Mar 29, 2019 Annual Review: Feb 14, 2022, [Cited 08/07/2024]
19. Aetna, Tumor Marker, [Number: 0352](#), Next review 04/10/2025. [Cited 07/30/2024]
20. Cigna, Molecular Diagnostic Testing for Hematology and Oncology Indications, Effective Date: 05/15/2025, Next review: 05/15/2025, Policy Number [0520](#). [Cited 07/30/2024]
21. Humana, Laboratory Analysis for Prostate Cancer, Policy Number: HUM-0594-010, Review Date: 07/27/2023 Effective date: 12/14/2023. [Cited 07/30/2024]
22. Humana, Gene Expression Profiling for Prostate Cancer, Policy Number: HUM-0602-004, Effective Date: 09/08/2023, Review Date: 08/24/2023. [Cited 07/30/2024]
23. UHC, Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions, Policy Number: 2024T0588EE, Effective Date: 07/01/2024 [Cited 08/07/2024]

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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 the mentioned codes above plus these codes will require PA 0047U, 81163, 81164, 81165, 81166, 81167, 0005U, 81539 and 81542. Restructured the policy for easier 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.
 - ProgenSA 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 BRACAnalysis 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 MoIDx: 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 MoIDx: Oncotype DX AR-V7 Nucleus Detect for Men with Metastatic Castrate Resistant Prostate Cancer (MCRPC) (L37915) now with a new title MoIDx: 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.
- **Progenesa 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.

08/21/2024

Annual review. Reviewed by PHP Medical Policy Committee on 08/07/2024. The following were updated.

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Diagnostic Testing:

- **ProgenSA PCA3: Updated** policy to follow Novitas LCD (L35396) and LCA (A52986) for ALOB. References in coding were reduced to avoid numerous repeat information in policy. No additional changes were made. This does not significantly impact coverage criteria.
- **For BRCA ½, ConfirmMDx, ExoDx Prostate (EPI) Test, and SelectMDx: No changes** to coverage guidance or criteria. References in coding were reduced to avoid numerous repeat information in policy. No additional changes were made.
- **Myprostatescore (MPS): Change.** Previously covered but now has moved to non-covered test for ALOB.

Treatment:

No changes to coverage guidance or criteria. References in coding were reduced to avoid numerous repeat information in policy. No additional changes were made to covered or non-covered tests. Overall, this policy was reviewed for grammatical and clarifying corrections throughout.

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.