

<b>Policy Name:</b>	<b>Medical Policy: Prostate Cancer Prognostic Tests Prebiopsy/Repeat Biopsy: 4K Score, ConfirmMDX, PCA3 Assay, Prostate Health Index, ExoDx Prostate, Select MDx</b>	<b>Policy #:</b>	<b>MP-318</b>
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## Policy Information

<b>Owner Department:</b>	Medical UM & Systems Department
<b>Owner:</b>	Assigned Medical Director
<b>Electronic Signature/Date:</b>	Krystal Revai (03/01/2023), Lori Slaughter (02/27/2023)

*If there is a discrepancy between a medical policy and a patient's policy or plan document/summary plan description, the policy or plan document/summary plan descriptions provisions and limitations will govern the determination of benefits.*

## Purpose of the Policy

To make utilization decisions, Health Alliance uses written criteria based on sound clinical evidence for appropriately applying the criteria.

## Statement of the Policy

To make utilization decisions, Health Alliance uses written criteria based on sound clinical evidence for appropriately applying the criteria.

**NOTE: Please refer to plan documents for prior authorization necessity/status.**

## Interpretations

- 1.1 **Health Alliance uses eviCore criteria to determine the medical necessity of Prostate Cancer Prognostic Tests performed pre-biopsy or when considering repeat biopsy.** The eviCore criteria are available on the [eviCore.com](https://www.eviCore.com) website and can be accessed by providers when submitting an authorization digitally.
- 1.2 **For Prognostic Tumor Tissue-Based tests for individuals with known prostate cancer, these test are adjudicated through eviCore.** The eviCore criteria can be accessed on the Health Alliance/eviCore provider prior-authorization portal. Please refer to Technology Topics, "Prostate Prognostic Tumor Tissue-Based Molecular Assays for Prostate Cancer" e.g. Decipher (81479), OncotypeDx Prostate (0047U), Prolaris (81541), and ProMark (81479).

**For Medicare criteria, Regional LCDs vary significantly related to these separate tests, review carefully.**

- Noridian (WA)
  - [Article - Billing and Coding: MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer \(A58724\) \(cms.gov\)](#)
  - [LCD - MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells \(L38645\) \(cms.gov\)](#)
  - [LCD - MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease \(L38341\) \(cms.gov\)](#)

- [LCD - MolDX: 4Kscore Assay \(L37122\) \(cms.gov\)](#)
- WPS (IA)
  - [LCD - MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer \(L39042\) \(cms.gov\)](#)
  - [Article - Response to Comments: MoLDX-CDD: Genomic Health™ Oncotype DX® Prostate Cancer Assay \(L36789\) \(A55396\) \(cms.gov\)](#)
  - [LCD - MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease \(L38433\) \(cms.gov\)](#)
- NGS (IL)
  - [Biomarker Testing LCD - Biomarker Testing \(Prior to Initial Biopsy\) for Prostate Cancer Diagnosis \(L37733\) \(cms.gov\) Molecular Pathology Procedures](#)
  - [Article - Billing and Coding: Molecular Pathology Procedures \(A56199\) \(cms.gov\)](#)
  - [Article - Billing and Coding: Biomarker Testing for Prostate Cancer Diagnosis \(A56609\) \(cms.gov\)](#)
- Palmetto (NC)
  - [Article - Billing and Coding: MoLDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer \(A58700\) \(cms.gov\)](#)
  - [Article - Billing and Coding: MoLDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease \(A58343\) \(cms.gov\)](#)

## CPT Codes

0005U	ExoDx (Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF, urine, algorithm reported as a risk score
81313	PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 3 [prostate specific antigen])ratio (e.g., prostate cancer)
81479	Select MDX (Unlisted molecular pathology procedure)
81539	4K Score (Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA, and human kallikrein-2 [hK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score)
81551	Confirm MDx (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)

Providers are required to indicate the diagnosis and procedure codes when requesting review of coverage.

## References

1. "NCCN Guidelines™ Version 2.2017: Prostate Cancer Early Detection". (February 21, 2017). National Comprehensive Cancer Network.
2. Hoffman RM. "Screening for prostate cancer". In: UpToDate, Post TW (Ed.); UpToDate, Waltham, MA. (Accessed 11/21/2017)
3. Hayes, Inc. Hayes Search & Summary. *4Kscore Test (OPKO Lab) for Prostate Cancer*. Lansdale, PA: Hayes, Inc. March, 2016.
4. Hayes, Inc. Hayes Genetic Testing Evaluation Report. *PCA2 Detection Test for Prostate Cancer*. Lansdale, PA; Hayes, Inc. June, 2014.
5. Hayes, Inc. Hayes Genetic Testing Evaluation Report. *ConfirmMDx for Prostate Cancer*. Lansdale, PA: Hayes, Inc. October, 2016.

## History

<b>Created Date:</b>	12/13/17	
<b>Effective Date:</b>	12/20/19	
<b>Next Review Date:</b>	03/01/2024	
<b>Revision Date:</b>	12/20/18 – MDC-Additional tests added.	
	12/17/19 – MDC - annual review, pointed to eviCore.	
	12/15/20 – MDC-Annual review, no changes, Medicare links updated.	
	12/21/21 – MDC-Annual review, no changes, links updated.	
	02/21/23 – MDC-Annual review, PA statement added to statement of policy, Medicare links updated.	