Genetic and Protein Biomarkers for the Diagnosis and Cancer Risk Assessment of Prostate Cancer

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider select genetic and protein biomarker testing of an individual aged 40-85 prior to an initial prostate biopsy to be eligible for coverage when ALL of the selection criteria are met:

- Confirmed moderately elevated PSA > 3 and < 10 ng/mL; AND
- Has not had a prostate biopsy; AND
- One of the following tests is requested as part of a shared decision-making process regarding whether to proceed with prostate biopsy:
  - Prostate Health Index (PHI)
  - 4Kscore® Test
  - SelectMDx (HOXC6 and DLX1 testing)
  - ExoDx Prostate IntelliScore (EPI; PCA3, ERG, and SPDEF RNA expression in exosomes)
  - MyProstateScore (MPS)
  - IsoPSA; AND
- The patient has not been previously tested using the same or similar biomarker test from the same sample or for the same clinical indication, AND
- The patient does not have an established diagnosis of prostate cancer; AND
Patient is candidate for prostate biopsy (i.e., has greater than a 10-year life expectancy) and would benefit from treatment of prostate cancer; AND

The medical records support the medical necessity for the test, including documented evidence of shared decision making between the patient and provider.

Note:
PSA elevation should be verified after a few weeks under standardized conditions (e.g. no ejaculation, manipulations, and urinary tract infections, no medications such as 5α-reductase) in the same laboratory or other Clinical Laboratory Improvement Amendments (CLIA) approved laboratory before considering a biopsy.

4Kscore Test Algorithm must contain all of the following components:
- 4 Kallikreins proteins (tPSA, fPSA, iPSA and hK2)
- Clinical information including age
- DRE
- Prior biopsy history

Based on review of available data, the Company may consider select genetic and protein biomarker testing of an individual aged 40 to 85 years prior to repeat prostate biopsy to be eligible for coverage** when ALL of the selection criteria are met:

- Confirmed moderately elevated PSA > 3 and < 10 ng/mL; AND
- Had negative or non-malignant prostate biopsy and repeat biopsy is considered within 24-months of the prior biopsy; AND
- One of the following tests is requested as part of a shared decision-making process regarding whether to proceed with prostate biopsy:
  - Prostate Health Index (PHI)
  - 4Kscore‡ Test
  - ExoDx Prostate IntelliScore (EPI)
  - Progensa® PCA3
  - ConfirmMDx (gene hypermethylation testing)
  - MyProstateScore (MPS)
  - IsoPSA; AND
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- The patient has not been previously tested using the same or similar biomarker test from the same sample or for the same clinical indication, AND
- The patient does not have an established diagnosis of prostate cancer; AND
- Patient is candidate for prostate biopsy (i.e., has greater than a 10-year life expectancy) and would benefit from treatment of prostate cancer; AND
- The medical records support the medical necessity for the test, including documented evidence of shared decision making between the patient and provider.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers all other uses of genetic and protein biomarkers for the diagnosis of prostate cancer to be investigational*, including but not limited to:
- Autoantibodies ARF6, Nkx3-1, 5' UTR-Bmi1, CEP 164, 3' UTR-Ropporin, Desmocollin, AURKAIP-1, and CSNK2A2 (eg, Apifiny)
- Sentinel PCa Test
- Mitochondrial DNA variant testing (eg, Prostate Core Mitomics Test)
- PanGIA Prostate
- Candidate gene panels
- NeoLAB™ Prostate Liquid Biopsy

Based on review of available data, the Company considers single nucleotide variant testing for cancer risk assessment of prostate cancer to be investigational.*

Policy Guidelines
Genetic Counseling
Experts recommend formal genetic counseling for individuals who are at risk for inherited disorders and who wish to undergo genetic testing. Interpreting the results of genetic tests and understanding risk factors can be difficult for some patients; genetic counseling helps individuals understand the impact of genetic testing, including the possible effects the test results could have on the individual or their family members. It should be noted that genetic counseling may alter the utilization of genetic testing substantially and may reduce inappropriate testing; further, genetic counseling should
be performed by an individual with experience and expertise in genetic medicine and genetic testing methods.

**Background/Overview**

**Prostate Cancer**

Prostate cancer is the most common cancer, and the second most common cause of cancer death in men. Prostate cancer is a complex, heterogeneous disease, ranging from microscopic tumors unlikely to be life-threatening to aggressive tumors that can metastasize, leading to morbidity or death. Early localized disease can usually be treated with surgery and radiotherapy, although active surveillance may be adopted in men whose cancer is unlikely to cause major health problems during their lifespan or for whom the treatment might be dangerous. In patients with inoperable or metastatic disease, treatment consists of hormonal therapy and possibly chemotherapy. The lifetime risk of being diagnosed with prostate cancer for men in the U. S. is approximately 16%, while the risk of dying of prostate cancer is 3%. African American men have the highest prostate cancer risk in the U. S.; the incidence of prostate cancer is about 60% higher and the mortality rate is more than 2 to 3 times greater than that of white men. Autopsy results have suggested that about 30% of men over the age of age 55 and 60% of men over the age of age 80 who die of other causes have incidental prostate cancer, indicating that many cases of cancer are unlikely to pose a threat during a man’s life expectancy.

**Grading**

The most widely used grading scheme for prostate cancer is the Gleason system. It is an architectural grading system ranging from 1 (well-differentiated) to 5 (undifferentiated); the score is the sum of the primary and secondary patterns. A Gleason score of 6 or less is low-grade prostate cancer that usually grows slowly; 7 is an intermediate grade; 8 to 10 is high-grade cancer that grows more quickly. A revised prostate cancer grading system has been adopted by the National Cancer Institute and the World Health Organization. A cross-walk of these grading systems is shown in Table 1.

**Table 1. Prostate Cancer Grading Systems**

<table>
<thead>
<tr>
<th>Grade Group</th>
<th>Gleason Score (Primary and Secondary Pattern)</th>
<th>Cells</th>
</tr>
</thead>
</table>

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Numerous genetic alterations associated with the development or progression of prostate cancer have been described, with the potential for the use of these molecular markers to improve the selection process of men who should undergo prostate biopsy or rebiopsy after an initial negative biopsy.

**FDA or Other Governmental Regulatory Approval**

**U.S. Food and Drug Administration (FDA)**

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). Laboratories that offer laboratory-developed tests must be licensed under the CLIA for high-complexity testing. The following laboratories are certified under the CLIA: BioReference Laboratories and GenPath Diagnostics (subsidiaries of OPKO Health; 4Kscore®, ARUP Laboratories, Mayo Medical Laboratories, LabCorp, BioVantra, others (PCA3 assay), Clinical Research Laboratory (Prostate Core Mitomic Test™), MDx Health (SelectMDx, ConfrirMDx), Innovative Diagnostics (phi™), and ExoDx® Prostate (Exosome Diagnostics). To date, the U.S. FDA has chosen not to require any regulatory review of these tests. In February 2012, the Progensa® PCA3 Assay (Gen-Probe; now Hologic) was approved by the FDA through the premarket approval process. The Progensa PCA3 Assay has been approved by the FDA to aid in the decision for repeat biopsy in men 50 years or older who have had 1 or more negative prostate biopsies and for whom a repeat biopsy would be recommended based on the current standard of care. The Progensa PCA3 Assay should not be used for men with atypical small acinar proliferation on their most recent biopsy. FDA product code: OYM.

In June 2012, proPSA, a blood test used to calculate the Prostate Health Index (PHI; Beckman Coulter) was approved by the FDA through the premarket approval process. The PHI test is indicated as an aid to distinguish prostate cancer from a benign prostatic condition in men ages 50 and older.

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Various genetic and protein biomarkers are associated with prostate cancer. These tests have the potential to improve the accuracy of differentiating between which men should undergo prostate biopsy and which rebiopsy after a prior negative biopsy. This evidence review addresses these types of tests for cancer risk assessment.

For individuals who are being considered for an initial prostate biopsy who receive testing for genetic and protein biomarkers of prostate cancer (eg, kallikreins biomarkers and 4Kscore Test, proPSA and Prostate Health Index, TMPRSS fusion genes and MyProstate score, SelectMDx for Prostate Cancer, ExoDx Prostate, Apifiny, PCA3 score, and PanGIA Prostate), the evidence includes systematic reviews, meta-analyses, and primarily observational studies. Relevant outcomes are overall survival, disease-specific survival, test validity, resource utilization, and quality of life. The evidence supporting clinical utility varies by the test but has not been directly shown for any biomarker test. Absent direct evidence of clinical utility, a chain of evidence might be constructed. However, the performance of biomarker testing for directing biopsy referrals is uncertain. While some studies have shown a reduction or delay in biopsy based on testing, a chain of evidence for clinical utility cannot be constructed due to limitations in clinical validity. Test validation populations have included men with a positive digital rectal exam, a prostate-specific antigen level outside of the gray zone (between 3 or 4 ng/mL and 10 ng/mL), or older men for whom the information from test results are less likely to be informative. Many biomarker tests do not have standardized cutoffs to recommend a biopsy. In addition, comparative studies of the many biomarkers are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
NeoLAB™ Prostate Liquid Biopsy (NeoGenomics Laboratories, Inc.) is a quantitative real-time PCR (qRT-PCR) test designed to look at expression levels of the genes AR, B2M, ERG, GAPDH, HSPD1, IMPDH2, PCA3, PDLIM5, PSA, PTEN, TMPRSS2, and UAP1 in urine and plasma samples. The expression levels of these genes is used in 2 different algorithms to determine patients prostate cancer risk assessment. It was noted that NeoLAB Prostate differentiates non-cancer and low-risk cancers from high-risk prostate cancer, reducing the need for unnecessary biopsies. Clinical utility studies using this assay results for decision-making for initial biopsy or repeat biopsy were not identified. In addition, no studies were identified that reported on health outcomes such as recurrence or survival of patients that underwent testing. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

For individuals who are being considered for repeat biopsy who receive testing for genetic and protein biomarkers of prostate cancer (e.g., PCA3 score, Gene Hypermethylation and ConfirmMDx test, Prostate Core Mitomics Test), the evidence includes systematic reviews and meta-analyses and primarily observational studies. Relevant outcomes are overall survival, disease-specific survival, test validity, resource utilization, and quality of life. The performance of biomarker testing for guiding rebiopsy decisions is lacking. The tests are associated with a diagnosis of prostate cancer and aggressive prostate cancer, but studies on clinical validity are limited and do not compare performance characteristics with standard risk prediction models. Direct evidence supporting clinical utility has not been shown. No data are currently available on physician decisions on rebiopsy or on the longer-term clinical outcomes of men who did not have a biopsy based on test results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Supplemental Information**
**Practice Guidelines and Position Statements**
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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American Urological Association et al
The American Urological Association (AUA, 2013; confirmed 2018) published guidelines on the early detection of prostate cancer. The AUA concluded that: “the literature supporting the efficacy of digital rectal exam (DRE), PSA [prostate-specific antigen] derivatives and isoforms (e.g. free PSA, -2proPSA, prostate health index, hK2 [human kallikrein 2], PSA velocity or PSA doubling time) and novel urinary markers and biomarkers (e.g. PCA3) for screening with the goal of reducing prostate cancer mortality provide limited evidence to draw conclusions. While some data suggest use of these secondary screening tools may reduce unnecessary biopsies (i.e. reduce harms) while maintaining the ability to detect aggressive prostate cancer (i.e. maintain the benefits of PSA screening), more research is needed to confirm this.”

National Comprehensive Cancer Network
The National Comprehensive Cancer Network (NCCN) guidelines (v.1.2022) recommend that any man with a PSA level greater than 3 ng/mL undergo workup for benign disease, repeat PSA, and digital rectal examination. Multiparametric MRI is recommended if available and can consider biomarkers that improve the specificity of screening.

The guidelines state that biomarkers that improve the specificity of detection are not, as yet, mandated as first-line screening tests in conjunction with serum PSA. However, there may be some patients who meet PSA standards for consideration of prostate biopsy, but for whom the patient and/or the physician wish to further define risk.

Several biomarker tests have been developed with the goals of refining patient selection for biopsies, decreasing unnecessary biopsies, and increasing the specificity of cancer detection, without missing a substantial number of higher-grade (2 or higher) cancers. These tests may be especially useful in individuals with PSA levels between 3 and 10 ng/mL. Most often these tests have been used in patients who have had one negative biopsy to determine if repeat biopsy is an appropriate consideration.

The panel recommends consideration of biomarker tests that have been validated in peer-reviewed, multi-site studies using an independent cohort of patients. These include percent free PSA (%f PSA), which may improve cancer detection and the Prostate Health Index (PHI), SelectMDx, 4Kscore®, or ExoDx Prostate Test (EPI), which may further define the probability of Grade Group 2 or higher cancers in patients with PSA levels > 3 ng/mL, who have not yet had a biopsy. %f PSA, PHI,
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4Kscore, EPI, PCA3, and ConfirmMDx may also be considered for those who have had at least one prior negative biopsy and are thought to be at higher risk. Extent of validation of these tests across diverse populations is variable. It is not yet known how such tests could be applied in optimal combination with MRI.

The panel could not recommend routine use of additional biomarker tests at this time (i.e., Mi-Prostate Score, Sentinel PCa Test).

The guidelines recommend as part of the workup for benign disease, consider biomarkers that improve the specificity of screening that includes percent free PSA, with consideration of the Prostate Health Index (PHI), SelectMDx, 4K score, ExoDx Prostate IntelliScore (EPI), MyProstate Score (MPS), and IsoPSA in patients who have not yet had a biopsy. NCCN noted that these tests may be especially useful in men with PSA levels between 3 ng/mL and 10 ng/mL. NCCN also noted that it is not yet known how these tests could be applied in optimal combination with magnetic resonance imaging (MRI).

For men who had a negative biopsy but are thought to be at higher risk, NCCN recommends to consider biomarkers that improve the specificity of screening (category 2A evidence). Tests that should be considered in the post-biopsy setting include percent free PSA 4Kscore, PHI, PCA3, ExoDx Prostate IntelliScore (EPI), MPS, IsoPSA and ConfirmMDx.

National Institute for Health and Care Excellence
In 2019 and in 2021, when guidelines were updated, the National Institute for Health and Care Excellence (NICE) did not recommend the Progensa PCA3 Assay or the PHI test for use in men with suspicion of prostate cancer who had a negative or inconclusive prostate biopsy.

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force (2018) updated recommendations for prostate cancer screening. Genetic and protein biomarkers addressed in this evidence review, including PCA3, were not mentioned.

The U.S. Preventive Services Task Force advises individualized decision making about screening for prostate cancer after discussion with a clinician for men ages 55 to 69 (C recommendation) and recommends against PSA-based screening in men 70 and older (D recommendation).
Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00773773</td>
<td>A Study to Assess if a Combination of Serum Measurements of Molecular Biomarkers and Serum Protein Profiling Can be Used to Predict Which Patients Undergoing Prostatic Biopsy Will be Diagnosed With Cancer</td>
<td>500</td>
<td>Oct 2022</td>
</tr>
<tr>
<td>NCT04100811</td>
<td>Validating the miR Scientific Sentinel™ Platform (Sentinel PCC4 Assay) in Men Undergoing Core Needle Biopsy Due to Suspicion of Prostate Cancer for Distinguishing Between no Cancer, Low-, Intermediate- and High-Risk Prostate Cancer</td>
<td>4000</td>
<td>Dec 2023</td>
</tr>
<tr>
<td>NCT04079699</td>
<td>Predicting Prostate Cancer Using a Panel of Plasma and Urine Biomarkers Combined in an Algorithm in Elderly Men Above 70 Years</td>
<td>700</td>
<td>Oct 2039</td>
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<tr>
<td>NCT05050084</td>
<td>Parallel Phase III Randomized Trials of Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-Intensification and Intensification Clinical Trial Evaluation (GUIDANCE)</td>
<td>2050</td>
<td>Apr 2037</td>
</tr>
</tbody>
</table>
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NCT: national clinical trial.
\(^a\) Denotes industry-sponsored or cosponsored trial.

References


37. White J, Shenoy BV, Tutrone RF, et al. Clinical utility of the Prostate Health Index (phi) for biopsy decision management in a large group urology practice setting. Prostate Cancer Prostatic Dis. Apr 2018; 21(1): 78-84. PMID 29158509


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76. LCD - MolDX: ConfirmMDx Epigenetic Molecular Assay (L37005) (cms.gov).


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Policy History
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10/14/2010 Medical Policy Committee review
10/06/2011 Medical Policy Committee review
10/19/2011 Medical Policy Implementation Committee approval. Minor change to coverage statement (“prognosis” added to the investigational statement on PCA3).
10/11/2012 Medical Policy Committee review
10/31/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/19/2013 Coding updated
10/03/2013 Medical Policy Committee review
10/16/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/04/2014 Medical Policy Committee review
08/06/2015 Medical Policy Committee review
08/19/2015 Medical Policy Implementation Committee approval. Added Kallikrein markers (4Kscore test), metabolomics profiles (Prostarix), candidate gene panels, mitochondrial DNA mutation testing (Prostate Core Mitomics test), and gene hypermethylation testing (ConfirmMDx) to INV statement. Title change.
10/06/2016 Medical Policy Committee review
10/19/2016 Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update
01/05/2017 Medical Policy Committee review
01/18/2017 Medical Policy Implementation Committee approval. Added Prostate Health Index (phi) to investigational statement and rationale. Updated rationale and references.
01/04/2018 Medical Policy Committee review
01/17/2018 Medical Policy Implementation Committee approval. Policy revised to separate initial biopsy and repeat biopsy populations, policy statement otherwise unchanged.
10/29/2018 Coding update
01/10/2019 Medical Policy Committee review
01/23/2019 Medical Policy Implementation Committee approval. The SelectMDx, ExoDx Prostate (IntelliScore), and Apifiny tests added as investigational.
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01/03/2020 Medical Policy Committee review
01/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged
02/04/2021 Medical Policy Committee review
02/10/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged
05/06/2021 Medical Policy Committee review
05/12/2021 Medical Policy Implementation Committee approval. PanGIA Prostate added as investigational.
05/05/2022 Medical Policy Committee review
05/11/2022 Medical Policy Implementation Committee approval. NeoLAB Prostate Liquid Biopsy was added as investigational.
10/06/2022 Medical Policy Committee review
10/12/2022 Medical Policy Implementation Committee approval. Coverage changed from investigational to eligible with criteria due to senate bill requirements.
12/01/2022 Medical Policy Committee review
12/14/2022 Medical Policy Implementation Committee approval. Senate bill update. Added MyProstateScore (MPS) and IsoPSA as eligible for coverage.
12/19/22 Coding update

Next Scheduled Review Date: 12/2023

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2021 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);

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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.