Medical Coverage Policy | Gene Expression Profiling and Protein Biomarkers for Prostate Cancer Management

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OVERVIEW

Gene expression profile analysis and protein biomarkers have been proposed as a means to risk-stratify patients with prostate cancer to guide treatment decisions. These tests are intended to be used either on prostate needle biopsy tissue to guide management decisions for active surveillance or therapeutic intervention, to guide radiotherapy use after radical prostatectomy (RP), or to guide medication selection after progression in metastatic castration-resistant prostate cancer.

The following tests are addressed in this policy:

- Decipher Biopsy (Veracyte, Inc.)
- Decipher RP (Veracyte, Inc.)
- Oncotype DX AR-V7 Nuclear Detect (Genomic Health)
- Oncotype DX Prostate (Genomic Health)
- Prolaris (Myriad)
- ProMark (Metamark Genetics)

MEDICAL CRITERIA

Medicare Advantage Plans

Decipher Biopsy, Prolaris and Oncotype DX Prostate

Decipher Biopsy, Prolaris and Oncotype DX Prostate are considered medically necessary for individuals with prostate cancer with:

- Localized or biochemically recurrent adenocarcinoma of the prostate (i.e., no clinical evidence of metastasis), **and;**
- Who have a life expectancy of greater than or equal to 10 years if they are a candidate for and are considering (or being considered for) at least 1 of the following:
  - Conservative management and yet would be eligible for definitive therapy (radical prostatectomy (RP), radiation or brachytherapy), **or;**
  - Radiation therapy and yet would be eligible for the addition of a brachytherapy boost, **or;**
  - Radiation therapy and yet would be eligible for the addition of short-term androgen deprivation therapy (ADT), **or;**
  - Radiation therapy with short-term ADT yet would be eligible for the use of long-term ADT, **or;**
  - Radiation with standard ADT yet would be eligible for systemic therapy intensification using next generation androgen signaling inhibitors or chemotherapy, **or;**
  - Observation post-prostatectomy yet would be eligible for the addition of post-operative adjuvant radiotherapy, **or;**
  - Salvage radiotherapy post-prostatectomy yet would be eligible for the addition of ADT, **and**;
- The assay is performed on formalin-fixed paraffin embedded (FFPE) prostate biopsy tissue with at least 0.5 mm of linear tumor diameter or FFPE tissue from a prostate resection specimen, **and**;
- Result will be used to determine treatment according to established practice guidelines, **and**;
- Patient has not received pelvic radiation or ADT prior to the biopsy or prostate resection specimen, **and**;
- Patient is monitored for disease progression according to established standards of care.

OncotypeDX AR-V7 Nuclear Detect
OncotypeDX AR-V7 Nuclear Detect assay is considered medically necessary when ALL of the following are met:

- The patient has been diagnosed with cancer, **and**
- The specific cancer type has an associated biomarker, **and**
- The associated biomarker has already established clinical utility (CU) in the peer-reviewed published literature for the intended cancer type and for the specific indication in the intended patient population
    - The biomarker's CU may include any of the following: it can be used to diagnose, risk-stratify, predict, or monitor response to therapy, as recommended by national or society guidelines (i.e., American Society of Clinical Oncology (ASCO), National Comprehensive Cancer Network (NCCN)) , **and**
- At least 1 of the following criteria are met AND there is clear documentation of at least 1 of these in the medical record:
    - The patient's cancer has not previously been tested for the specific biomarker, OR
    - The patient has newly metastatic cancer, and a metastatic lesion has not been tested for the specific biomarker, OR
    - The patient demonstrates signs of clinical, radiological or pathologic disease progression, OR
    - There is concern for resistance to treatment based on specific and well-established clinical indications, **and**
- Testing for the biomarker can be performed using CTCs, **and**
- Tissue-based testing for the specific biomarker is infeasible (e.g., quantity not sufficient or invasive biopsy is medically contraindicated) OR will not provide sufficient information for subsequent medical management (e.g., in cases where human epidermal growth factor receptor 2 (HER2) overexpression is negative in a tissue biopsy but may be positive in the CTCs, due to tumor heterogeneity). There is clear documentation of at least 1 of these reasons for testing in the medical record, **and**
- For a given patient encounter, only 1 test for assessing the biomarker may be performed UNLESS a second test, meeting all the criteria established herein, is reasonable and necessary as an adjunct to the first test, **and**
- Duplicate testing of the same biomarker (from the same sample type and for the same clinical indication) using different methodologies is not covered. For example, testing for androgen receptor splice variant 7 (AR-V7) from CTCs by messenger RNA (mRNA) as well as immunohistochemistry (IHC)-based methodologies, for the same clinical indication, will not be covered.

Commercial Products
Unless otherwise noted, for any test filed with an Unlisted CPT code, the medical necessity criteria in the Genetic Testing Services policy would be used. Please see the Related Policies section.

PRIOR AUTHORIZATION

Medicare Advantage Plans
Prior authorization is required for Prolaris, Decipher, Oncotype DX Prostate, and OncotypeDX AR-V7 Nuclear Detect and is obtained via the online tool for participating providers.

Medicare Advantage Plans and Commercial Products
There is no specific CPT coding for some testing referenced in this policy. Therefore, an Unlisted CPT code should be used (See Coding Section for details). All Unlisted genetic testing CPT codes require prior authorization to determine what service is being rendered and if the service is covered or not medically necessary. See the Related Policies section.

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial products and is obtained via the online tool for participating providers. See the Related Policies section.

Note: Laboratories are not allowed to obtain clinical authorization or participate in the authorization process on behalf of the ordering physician. Only the ordering physician shall be involved in the authorization, appeal or other administrative processes related to prior authorization/medical necessity.

In no circumstance shall a laboratory or a physician/provider use a representative of a laboratory or anyone with a relationship to a laboratory and/or a third party to obtain authorization on behalf of the ordering physician, to facilitate any portion of the authorization process or any subsequent appeal of a claim where the authorization process was not followed and/or a denial for clinical appropriateness was issued, including any element of the preparation of necessary documentation of clinical appropriateness. If a laboratory or a third party is found to be supporting any portion of the authorization process, BCBSRI will deem the action a violation of this policy and severe action will be taken up to and including termination from the BCBSRI provider network. If a laboratory provides a laboratory service that has not been authorized, the service will be denied as the financial liability of the participating laboratory and may not be billed to the member.

POLICY STATEMENT

Medicare Advantage Plans

The following tests may be considered medically necessary when the medical criteria above are met:

- Prolaris
- Decipher Biopsy
- Oncotype DX Prostate
- Oncotype DX AR-V7 Nuclear Detect

The following tests are not covered as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome:

- Decipher RP
- ProMark

Commercial Products

The following tests are not medically necessary as the evidence is insufficient to that the technology results in an improvement in the net health outcome:

- Decipher Biopsy
- Decipher RP
- Oncotype DX Prostate
- Oncotype DX AR-V7 Nuclear Detect
- Prolaris
- ProMark

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable genetic testing and not medically necessary/not covered benefits/coverage.

BACKGROUND

Prostate cancer is the second most common noncutaneous cancer diagnosed among men in the United States. Autopsy studies in the era before the availability of prostate-specific antigen (PSA) screening have identified incidental cancerous foci in 30% of men 50 years of age, with incidence reaching 75% at age 80 years.

Localized prostate cancers may appear very similar clinically at diagnosis. However, they often exhibit diverse risk of progression that may not be captured by clinical risk categories (eg, D'Amico criteria) or prognostic tools based on clinical findings, including PSA titers, Gleason grade, or tumor stage. In studies of conservative management, the risk of localized disease progression based on prostate cancer–specific survival

rates at 10 years may range from 15% to 20% to perhaps 27% at 20-year follow-up. Among older men (ages ≥ 70 years) with low-risk disease, comorbidities typically supervene as a cause of death; these men will die with prostate cancer present, rather than from cancer itself. Other very similar appearing low-risk tumors may progress unexpectedly rapidly, quickly disseminating and becoming incurable.

Risk Stratification in Newly Diagnosed Disease
In the United States, most prostate cancers are clinically localized at diagnosis due in part to the widespread use of PSA testing. Clinicopathologic characteristics are used to stratify patients by risk based on the extent of the primary tumor (T category), nearby lymph node involvement (N category), metastasis (M category), PSA level and Gleason score. The National Comprehensive Cancer Network and American Urological Association risk categories for clinically localized prostate cancer are similar, derived from the D'Amico criteria and broadly include low-, intermediate-, or high-risk as follows as well as subcategories within these groups:

- Low: T1-T2a and Gleason score ≤6/Gleason grade group 1 and PSA level ≤10 ng/mL;
- Intermediate: T2b-T2c or Gleason score 3+4=7/Gleason grade group 2 or Gleason score 4+3=7/Gleason grade group 3 or PSA level 10-20 ng/mL;
- High: T3a or Gleason score 8/Gleason grade group 4 or Gleason score 9-10/Gleason grade group 5 or PSA level >20 ng/mL.

Risk stratification is combined with patient age, life expectancy, and treatment preferences to make initial therapy decisions.

Monitoring After Prostatectomy
All normal prostate tissue and tumor tissue are theoretically removed during radical prostatectomy (RP), so the serum level of PSA should be undetectable following RP. Detectable PSA post-RP indicates residual prostate tissue and presumably persistent or recurrent disease. PSA is serially measured following RP to detect early disease recurrence. The National Comprehensive Cancer Network recommends monitoring serum PSA every 6 to 12 months for the first 5 years and annually thereafter. Many recurrences following RP can be successfully treated. The American Urological Association has recommended that biochemical recurrence be defined as a serum PSA of 0.2 ng/mL or higher, which is confirmed by the second determination with a PSA level of 0.2 ng/mL or higher.

Castration-Resistant Prostate Cancer
Androgen deprivation therapy (ADT) is generally the initial treatment for patients with advanced prostate cancer. ADT can produce tumor response and improve quality of life but most patients will eventually progress on ADT. Disease that progresses while the patient is on ADT is referred to as castrationresistant prostate cancer. After progression, continued ADT is generally used in conjunction with other treatments. Androgen pathways are important in the progression of castration-resistant prostate cancer.
Several drugs have been developed that either inhibit enzymes involved in androgen production or inhibit the androgen receptor, such as abiraterone and enzalutamide. Taxane chemotherapy with docetaxel or cabazitaxel may also be used after progression. Immunotherapy (sipuleucel-T) or radium 223 are options for select men.

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). Prolaris® (Myriad Genetics), Oncotype DX® Prostate and Oncotype DX AR-V7 Nuclear Detect (Genomic Health), Decipher® gene expression profiling test (Decipher Corp), and the ProMark™ protein biomarker test (Metamark Genetics) are available under the auspices of CLIA. Laboratories that offer laboratory-developed tests must be licensed by CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration (FDA) has chosen not to require any regulatory review of this test.

Decipher Biopsy
Decipher® Prostate is a 22 gene genomic classifier microarray assay, measuring the expression of over 1.4 million RNAs (from coding and non-coding genes). The assay is performed on FFPE prostate cancer tumor tissue from diagnostic biopsy needle cores or prostate resection tissue (Transurethral resection (TUR) or

prostatectomy). The assay results are reported as a genomic classifier (GC) score based on gene expression using a machine-learning algorithm. The molecular pathways represented include proliferation/cell death, invasion & metastasis, androgen signaling, immune activity & response, growth & differentiation, angiogenesis and metabolism functions.

The test can be used to further risk stratify patients providing both a continuous score and a categorization of that score into low, average or high-risk with associated probabilities of high-grade disease, 5-year metastatic risk and 10-year prostate cancer specific mortality.

Medicare Advantage Plans
Numerous studies from different institutions have all had similar and consistent findings, providing evidence that this test accurately risk stratifies patients based on genetic information and accurately predicts risk of biochemical recurrence, metastatic disease, or prostate-cancer specific mortality. Given that existing treatment paradigms are heavily reliant upon risk assessment, the ability to accurately risk stratify has potential utility in the management of prostate cancer. As such, this test provides clinically actionable incremental information that fits into existing evidence-based or consensus-recommended prostate cancer treatment paradigms.

Commercial Products
For individuals who have clinically localized untreated prostate cancer who receive Decipher Biopsy, the evidence includes retrospective cohort studies of clinical validity using archived samples in intermediate- and high-risk patients and no studies of clinical utility. Relevant outcomes include OS, disease-specific survival, QOL, and treatment-related morbidity. A test designed to identify intermediate-risk men who can receive active surveillance instead of RP or radiotherapy (RT) or high-risk men who can forego androgen deprivation therapy would need to show very high negative predictive value for disease-specific mortality at 10 years and improvement in prediction compared with existing tools used to select such men. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Decipher RP
The Decipher test classifies as low-risk those patients who can delay or defer RT after prostatectomy, or as high-risk those who would potentially benefit from early radiation. The GC is a continuous risk score between 0 and 1, with higher risk scores indicating a greater probability of developing metastasis.

Medicare Advantage Plans and Commercial Products
For individuals who have localized prostate cancer who are treated with RP and who receive the Decipher RP prostate cancer classifier, the evidence includes a study of analytic validity, prospective and retrospective studies of clinical validity using overlapping archived samples, decision-curve analyses examining indirect evidence of clinical utility, and prospective decision-impact studies without pathology or clinical outcomes. Relevant outcomes include OS, disease-specific survival, QOL, and treatment-related morbidity. The clinical validity of the Decipher RP genomic classifier has been evaluated in samples of patients with high-risk prostate cancer undergoing different interventions following RP. Studies reported some incremental improvement in discrimination. However, it is unclear whether there is consistently improved reclassification-particularly to higher risk categories-or whether the test could be used to predict which men will benefit from radiotherapy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Oncotype DX Prostate
The Oncotype DX Prostate assay includes 5 reference genes and 12 cancer genes that represent 4 molecular pathways of prostate cancer oncogenesis: androgen receptor, cellular organization, stromal response, and proliferation. The assay results are combined to produce a Genomic Prostate Score (GPS), which ranges from 0 to 100. Higher GPS scores indicate more risk.

Medicare Advantage Plans
Numerous studies from different institutions have all had similar and consistent findings, providing evidence that this test accurately risk stratifies patients based on genetic information and accurately predicts risk of

biochemical recurrence, metastatic disease, or prostate-cancer specific mortality. Given that existing treatment paradigms are heavily reliant upon risk assessment, the ability to accurately risk stratify has potential utility in the management of prostate cancer. As such, this test provides clinically actionable incremental information that fits into existing evidence-based or consensus-recommended prostate cancer treatment paradigms.

Commercial Products
For individuals who have clinically localized untreated prostate cancer who receive Oncotype DX Prostate, the evidence includes case-cohort and retrospective cohort studies of clinical validity using archived samples in patients of mixed risk categories, and a decision-curve analysis examining indirect evidence of clinical utility. Relevant outcomes include OS, disease-specific survival, QOL, and treatment-related morbidity. Evidence for clinical validity and potential clinical utility of Oncotype DX Prostate in patients with clinically localized prostate cancer derives from a study predicting adverse pathology after RP. The validity of using tumor pathology as a surrogate for the risk of progression and cancer-specific death is unclear. It is also unclear whether results from an RP population can be generalized to an active surveillance population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Oncotype DX AR-V7 Nuclear Detect
Oncotype DX AR-V7 Nuclear Detect is used to detect nuclear-localized AR-V7 protein in CTCs of men with mCRPC who have failed first-line therapy and are considering additional ARS inhibitor therapy.

Medicare Advantage Plans
The evidence to-date supports AR-V7 testing from CTCs in prostate cancer. In prostate cancer, the presence of AR-V7 from CTCs is currently the basis for making treatment decisions regarding taxane versus ARS inhibitor therapy and is recommended by NCCN guidelines.

Testing using this CTC-based biomarker test should successfully complete a comprehensive Technical Assessment (TA) by MolDX that will ensure that Analytical Validity (AV) (including an analytical and clinical validation), Clinical Validity (CV), and Clinical Utility criteria are met to establish the test as Reasonable and Necessary.

- The clinical validation should demonstrate performance that is equivalent or superior to tissue-based-testing or another already-accepted test for the same biomarker for the same intended use.
- CV (for new analytes) must be established through studies published in the peer-reviewed literature for the intended use of the test in the intended population.

Commercial Products
For individuals who have metastatic castration-resistant prostate cancer who receive the Oncotype DX AR-V7 Nuclear Detect, the evidence includes 1 prospective cohort study, 1 retrospective cohort study of clinical validity using archived samples, and no studies of clinical utility. Relevant outcomes include OS, disease-specific survival, QOL, and treatment-related morbidity. Current evidence does not support improved outcomes with Oncotype DX AR-V7 Nuclear Detect, given that only 2 clinical validity studies meeting inclusion criteria were available. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Prolaris
Prolaris is used to quantify expression levels of 31 cell cycle progression (CCP) genes and 15 housekeeper genes to generate a CCP score.

Medicare Advantage Plans
Numerous studies from different institutions have all had similar and consistent findings, providing evidence that this test accurately risk stratifies patients based on genetic information and accurately predicts risk of biochemical recurrence, metastatic disease, or prostate-cancer specific mortality. Given that existing treatment paradigms are heavily reliant upon risk assessment, the ability to accurately risk stratify has potential utility in the management of prostate cancer. As such, this test provides clinically actionable incremental information that fits into existing evidence-based or consensus-recommended prostate cancer treatment paradigms.

Commercial Products
For individuals who have clinically localized untreated prostate cancer who receive Prolaris, the evidence includes retrospective cohort studies of clinical validity using archived samples in patients of mixed risk categories. Relevant outcomes include overall survival (OS), disease-specific survival, quality of life (QOL), and treatment-related morbidity. For the low-risk group, the Prostate Testing for Cancer and Treatment trial showed 99% 10-year disease-specific survival in mostly low-risk patients receiving active surveillance. The low mortality rate estimated with tight precision makes it unlikely that a test intended to identify a subgroup of low-risk men with a net benefit from immediate treatment instead of active surveillance would find such a group. For the intermediate-risk group, the evidence of improved clinical validity or prognostic accuracy for prostate cancer death using Prolaris Cell Cycle Progression score in patients managed conservatively after a needle biopsy has shown some improvement in areas under the receiver operating characteristic curve over clinicopathologic risk stratification tools. There is limited indirect evidence for potential clinical utility. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have localized prostate cancer treated with RP who receive Prolaris, the evidence includes retrospective cohort studies of clinical validity using archived samples. Relevant outcomes include OS, disease-specific survival, QOL, and treatment-related morbidity. No direct evidence is available to support the clinical utility of Prolaris for improving net outcomes of patients with localized prostate cancer following RP. The chain of evidence is also incomplete. Decision-curve analysis did not provide convincing evidence of meaningful improvement in net benefit by incorporating the cell cycle progression (CCP) score. Evidence of improved clinical validity or prognostic accuracy for prostate cancer death using the Prolaris Cell Cycle Progression score in patients after prostatectomy has shown some improvement in areas under the receiver operating characteristic curve over clinicopathologic risk stratification tools. Although Prolaris CCP score may have an association with biochemical recurrence (BCR), disease-specific survival outcomes were reported in only 1 analysis. A larger number of disease-specific survival events and precision estimates for discrimination measures are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

ProMark Protein Biomarker Test
The ProMark assay includes 8 biomarkers that predict prostate pathology aggressiveness and lethal outcomes: DERL1, PDSS2, pS6, YBX1, HSPA9, FUS, SMAD4, and CUL2. The assay results are combined using predefined coefficients for each marker from a logistic regression model to calculate a risk score. The risk score is a continuous number between 0 and 1, which estimates the probability of "non–GS 6" pathology.

Medicare Advantage Plans and Commercial Products
For individuals who have clinically localized untreated prostate cancer who receive the ProMark protein biomarker test, the evidence includes a retrospective cohort study of clinical validity using archived samples and no studies of clinical utility. Relevant outcomes include OS, disease-specific survival, QOL, and treatment-related morbidity. Current evidence does not support improved outcomes with ProMark given that only a single clinical validity study is available. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING
The following CPT codes may be medically necessary for Medicare Advantage Plans when the medical criteria above is met and are not medically necessary for Commercial Products.

This code can be used for the Prolaris Assay.

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

This code can be used for Decipher Biopsy.

81542 Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score

This code can be used for the Oncotype DX® Prostate.

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

The following Unlisted CPT code requires prior authorization for Medicare Advantage Plans and Commercial Products. The code can be used for any test identified in this policy that has not been assigned a specific CPT code.

81479 Unlisted molecular pathology procedure

RELATED POLICIES

Genetic Testing Services
Proprietary Laboratory Analyses (PLA)

PUBLISHED

Provider Update, June 2022
Provider Update, July 2021
Provider Update, May 2020
Provider Update, August 2019
Provider Update, November 2017

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