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

EFFECTIVE DATE: 09|01|2025
POLICY LAST REVIEWED: 05|07|2025

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 test(s) are addressed in this policy:

- ProMark (Metamark Genetics), CPT 81479

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

Effective 9/1/2025, the following test(s) are considered medically necessary when the medical criteria in the online authorization tool for participating providers is met:

- Decipher Prostate Genomic Classifier (Veracyte, Inc.), CPT Code 81542
- Genomic Prostate Score® (GPS) Test, MDxHealth, Inc, CPT Code 0047U
- Oncotype DX AR-V7 Nuclear Detect (Genomic Health), CPT Code 81479
- Prolaris (Myriad), CPT Code 81541

PRIOR AUTHORIZATION

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial Products for and is obtained via the online tool for participating providers for the following test(s):

- Decipher Prostate Genomic Classifier
- Genomic Prostate Score® (GPS) Test
- Oncotype DX AR-V7 Nuclear Detect
- Prolaris

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.

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 and Commercial Products

Effective 9/1/2025, the following test(s) may be considered medically necessary when the medical criteria above are met:

- Decipher Prostate Genomic Classifier
- Genomic Prostate Score® (GPS) Test
- Oncotype DX AR-V7 Nuclear Detect
- Prolaris

The following test(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome:

- ProMark

Commercial Products

Some genetic testing services are not covered and a contract exclusion for any self-funded group that has excluded the expanded coverage of biomarker testing related to the state mandate, R.I.G.L**. §27-19-81** described in the Biomarker Testing Mandate policy. For these groups, a list of which genetic testing services are covered with prior authorization, are not medically necessary or are not covered because they are a contract exclusion can be found in the Coding section of the Genetic Testing Services or Proprietary Laboratory Analyses policies. Please refer to the appropriate Benefit Booklet to determine whether the member's plan has customized benefit coverage. Please refer to the list of Related Policies for more information.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable laboratory 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 castration-resistant 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). The ProMark™ protein biomarker test (Metamark Genetics) is 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 these tests.

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.

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
Effective 9/1/2025, the following CPT code(s) may be medically necessary for Medicare Advantage Plans and Commercial Products when the medical criteria in the online authorization tool for participating providers is met.

- Decipher Prostate Genomic Classifier, CPT 81542

- Genomic Prostate Score® (GPS) Test, CPT 0047U (Test Name and Laboratory Revised Effective 7/1/2024)
- Oncotype DX AR-V7 Nuclear Detect, CPT 81479
- Prolaris, CPT 81541

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 (e.g. Promark) that has not been assigned a specific CPT code.
81479 Unlisted molecular pathology procedure

RELATED POLICIES
Biomarker Testing Mandate
Genetic Testing Services
Proprietary Laboratory Analyses (PLA)
Unlisted Procedures

PUBLISHED
Provider Update, July 2025
Provider Update, September 2024
Provider Update, November 2023
Provider Update, June 2022
Provider Update, July 2021

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