

Genomic Prostate Score

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Procedures addressed

The inclusion of any procedure code in this table does not imply that the code is under management or requires prior authorization. Refer to the specific Health Plan's procedure code list for management requirements.

Procedures addressed by this guideline	Procedure codes
Genomic Prostate Score (formerly OncotypeDX Genomic Prostate Score)	0047U

Criteria

Introduction

Requests for Genomic Prostate Score testing are reviewed using the following criteria. This test is considered Experimental, Investigational, or Unproven.

- Experimental, Investigational, or Unproven (E/I/U) refers to tests, or uses of tests, that have insufficient data to demonstrate an overall health benefit. This typically means there is insufficient data to support that a test accurately assesses the outcome of interest (analytical and clinical validity) and significantly improves patient health outcomes (clinical utility). Such tests are also not generally accepted as the standard of care in the evaluation or management of a particular condition.
- In the case of laboratory testing, FDA approval or clearance is not a reliable standard given the number of laboratory developed tests that currently fall outside of FDA oversight. In addition, FDA approval or clearance often does not include an assessment of clinical utility.

What are gene expression profiling tests for prostate cancer?

Prostate cancer (PC) is the most common cancer in men, and metastatic prostate cancer is a leading cause of cancer-related deaths worldwide. It is considered a heterogeneous disease with highly variable prognosis.¹

- At the time of diagnosis of localized PC, patients typically undergo a prognostic risk assessment with routine clinical and pathological tests to assess the probability of

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subsequent progression or metastasis. These prognostic assessments help to identify lower risk patients with indolent disease who may opt for active surveillance (AS), or higher risk patients with more aggressive disease who may benefit from a treatment intervention.

- High-risk prostate cancer (PC) patients treated with radical prostatectomy (RP) also undergo risk assessment to assess future disease prognosis and determine optimal treatment strategies. Post-RP pathology findings, such as disease stage, baseline Gleason score, time of biochemical recurrence (BCR) after RP, and PSA doubling-time, are considered strong predictors of disease-associated metastasis and mortality. Following RP, up to 50% of patients have pathology or clinical features that are considered at high risk of recurrence and these patients usually undergo post-RP treatments, including adjuvant or salvage therapy or radiation therapy, which can have serious risks and complications. According to clinical practice guideline recommendations, high risk patients should undergo 6 to 8 weeks of radiation therapy (RT) following RP. However, approximately 90% of high-risk patients do not develop metastases or die of prostate cancer, and instead may be appropriate candidates for alternative treatment approaches, including AS. As such, many patients may be subjected to unnecessary follow-up procedures and their associated complications, highlighting the need for improved methods of prognostic risk assessment.^{2,3}
- Several genomic biomarkers have been commercially developed to augment the prognostic ability of currently available routine clinical and pathological tests and identify those patients either at the time of diagnosis of localized PC or after radical prostatectomy (RP) most and least likely to benefit from a specific treatment strategy. Prognostic genomic tests, including gene expression profiling tests, may help to avoid overtreatment by reclassifying those men originally identified as high risk, but who are unlikely to develop metastatic disease. Genomic biomarkers may also play a role in assisting clinicians to tailor personalized and more appropriate treatments for subgroups of PC patients, and improve overall health outcomes.^{2,3}

Test information

- Gene expression profiles (GEPs) evaluate the expression of several genes using one sample. Gene expression is determined through RNA analysis, using either reverse transcriptase (RT) polymerase chain reaction (PCR) or DNA microarrays.⁴
- The Genomic Prostate Score test (GPS; formerly Oncotype DX GPS) is intended for "men with low-, intermediate-, and high-risk localized prostate cancer to help guide treatment decisions at the time of diagnosis. The test analyzes prostate cancer gene activity to predict disease aggressiveness and provide clinically meaningful endpoints."⁵

- The GPS test uses quantitative RT-PCR for 12 prostate cancer-related genes and 5 control genes (total of 17 genes). It was developed for use with formalin fixed paraffin-embedded (FFPE) diagnostic prostate needle biopsies (≥ 1 mm prostate tumor).⁵
- Results are expressed as a genomic prostate score, ranging from 0-100, representing tumor aggressiveness. The GPS test provides risk stratification to properly classify patients with regard to their risk of metastasis and death from prostate cancer. This test is designed to help patients with newly diagnosed, early-stage PC make informed treatment decisions, including active surveillance.⁵
- The GPS test reports the following endpoints:
 - "Risk of high-grade (>Grade Group 3) disease
 - Risk of pT3a+ disease
 - Risk of metastasis within 10 years
 - Risk of PCa-specific death within 10 years"

Guidelines and evidence

American Association of Clinical Urologists

The American Association of Clinical Urologists (AACU, 2018) has issued a position statement on genomic testing in prostate cancer that states the following:⁶

- "The AACU supports the use of tissue-based molecular testing as a component of risk stratification in prostate cancer treatment decision making."

American Society of Clinical Oncology

The American Society of Clinical Oncology (ASCO, 2020) issued a guideline in molecular biomarkers in prostate cancer. This guideline states:⁷

- "Are there molecular biomarkers to diagnose clinically significant prostate cancer?"
 - "Recommendation 2.1. Commercially available molecular biomarkers (ie, Oncotype Dx Prostate [now GPS], Prolaris, Decipher, and ProMark) may be offered in situations in which the assay result, when considered as a whole with routine clinical factors, is likely to affect management. Routine ordering of molecular biomarkers is not recommended (Type: Evidence based; Evidence quality: Intermediate; Recommendation: Moderate)."
 - "Recommendation 2.2. Any additional molecular biomarkers evaluated do not have sufficient data to be clinically actionable or are not commercially available and thus should not be offered (Type: Evidence based; Evidence quality: Insufficient; Strength of recommendation: Moderate)."
- "Are there molecular biomarkers to guide the decision of postprostatectomy adjuvant versus salvage radiation?"

- "Recommendation 3.1. The Expert Panel recommends consideration of a commercially available molecular biomarker (eg, Decipher Genomic Classifier) in situations in which the assay result, when considered as a whole with routine clinical factors, is likely to affect management. In the absence of prospective clinical trial data, routine use of genomic biomarkers in the postprostatectomy setting to determine adjuvant versus salvage radiation or to initiate systemic therapies should not be offered (Type: Evidence based; Evidence quality: Intermediate; Strength of recommendation: Moderate)."
- "Recommendation 3.2. Any additional molecular biomarkers evaluated do not have sufficient data to be clinically actionable or are not commercially available and thus should not be offered (Type: Evidence based; Evidence quality: Insufficient; Strength of recommendation: Moderate)."

American Urological Association and American Society of Radiation Oncology

The American Urological Association and American Society for Radiation Oncology (AUA/ASTRO, 2022) published an evidence-based guideline on localized prostate cancer endorsed by the Society of Urologic Oncology (SGO) that stated:⁸

- "Clinicians may selectively use tissue-based genomic biomarkers when added risk stratification may alter clinical decision-making. (Expert Opinion)"
- "Clinicians should not routinely use tissue-based genomic biomarkers for risk stratification or clinical decision-making. (Moderate Recommendation; Evidence Level: Grade B)"
- "Regarding tissue-based genomic biomarkers, several currently available commercial tests, including Prolaris, Oncotype Dx [now Genomic Prostate Score], and Decipher, variously offer prediction of adverse pathology as well as the risks of biochemical recurrence, metastasis, and prostate cancer death. However, most of the reported studies to date that evaluated the prognostic ability of these genomic tests did not meet inclusion criteria for the systematic review as the studies used surgical (ie, prostatectomy) rather than biopsy specimens."

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN, 2025) Clinical Practice Guidelines on Prostate Cancer state the following regarding molecular assays:⁹

- "Retrospective case cohort studies have shown that these assays provide prognostic information independent of NCCN or CAPRA risk groups, which include likelihood of death with conservative management, likelihood of biochemical recurrence after radical prostatectomy or EBRT [external beam radiation therapy], likelihood of adverse pathologic features after radical prostatectomy, and likelihood of developing metastasis after operation, definitive EBRT, or post-recurrence EBRT."
- "These molecular biomarker tests have been developed with extensive industry support, guidance, and involvement, and have been marketed under the less rigorous

FDA regulatory pathways for biomarkers. Although full assessment of their clinical utility requires prospective randomized clinical trials, which are unlikely to be done, the panel believes that men with low or favorable intermediate disease and life expectancy greater than or equal to 10 years may consider the use of Decipher, Oncotype DX Prostate [now Genomic Prostate Score], or Prolaris during initial risk stratification. Patients with unfavorable intermediate- and high-risk disease and life expectancy greater than or equal to 10 years may consider the use of Decipher or Prolaris."

- NCCN does not include Genomic Prostate Score in its table of advanced molecular tools with evidence to support clinical use.

Selected Relevant Publications

Overall, the evidence base for the GPS test is large and of low quality.¹⁰⁻⁵⁴ Several studies reported that GPS improved prediction of adverse pathology beyond currently used clinical parameters and nomograms; however, these studies did not consistently report precision estimates, and when reported, wide confidence intervals suggested inadequate precision. Direct evidence of clinical utility for GPS is lacking. Indirect clinical utility studies suggest that GPS has an impact on physician and patient decision-making; however, there is limited evidence regarding whether these changes lead to relevant improvements in overall health. This conclusion is echoed by several systematic reviews.⁵⁵⁻⁵⁹ Additional well-designed studies are needed that evaluate health outcomes in patients whose clinical management decisions were determined by GPS test results.

Clinical trials may be ongoing. Additional information can be found at www.clinicaltrials.gov.

Note:

This benefit/harm statement only applies to those jurisdictions that do not have Medicare guidance. Based upon the guidelines and evidence provided in the clinical policy, following EviCore's criteria for Genomic Prostate Score will ensure that testing will be available to those members most likely to benefit from the information provided by evidence-supported assays. For members or assays not meeting criteria for coverage, it ensures alternate management strategies are considered. However, it is possible that some members who would benefit from the testing will not receive an immediate approval or will experience a delay in care while providers search for an appropriate test with sufficient evidence (analytical validity, clinical validity, and clinical utility).

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