

Prostate Cancer Treatment and Prognostic Algorithmic Tests

- I. The use of a prostate cancer treatment and prognostic algorithmic test (i.e., Genomic Prostate Score Test, Prolaris, Decipher, ArteraAI) is considered **medically necessary** when:
 - A. The member has prostate cancer, **AND**
 - B. The member has a life expectancy of 10 years or more, **AND**
 - C. The member does **not** have either of the following:
 1. Very low-risk prostate cancer, as defined by all of the following characteristics:
 - a) cT1c
 - b) Grade Group 1
 - c) PSA less than 10 mg/nl and density less than 0.15 ng/mL/g
 - d) Biopsy shows less than 3 positive cores/fragments and less than or equal to 50% cancer in each core/fragment, **OR**
 2. Very high-risk prostate cancer, as defined by all of the following characteristics:
 - a) cT3-cT4
 - b) PSA greater than 40 ng/mL
 - c) Grade Group 4 or 5.
- II. The use of a prostate cancer treatment and prognostic algorithmic test is considered **investigational** for all other indications.

RATIONALE AND REFERENCES

Prostate Cancer Treatment and Prognostic Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Prostate Cancer (2.2025)

This guideline recommends use of advanced risk stratification tools (i.e., gene expression biomarkers, AI digital pathology) for disease management, most commonly for men with localized prostate cancer and life expectancy of 10 yrs or more (p. PROS-4, 5, 6 of 7). The most common reasons to use these tools are for deciding between active surveillance and radical treatment, or use of radiation alone vs radiation with androgen deprivation therapy (short or long term) (p. PROS-H 2 and 3 of 7).

These tests should not be used for very low risk or very high risk disease as they have not been validated in these populations and there are no current treatment implications based on the results (p. PROS-H 1 of 7 and PROS-H 3, 4, 5, 6, of 7). The following tumor-based assays are called out for use: Decipher, Genomic Prostate Score (GPS), ArteraAI Prostate and Prolaris (p. PROS-H 3 of 7).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer 2.2025 https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

American Society of Clinical Oncology (ASCO)

ASCO issued a guideline called “Molecular Biomarkers in Localized Prostate Cancer: ASCO Guideline” (2020). The guideline overall states that tissue-based biomarker testing “may improve risk stratification”, but results should be interpreted in combination with other routine clinical factors (p. 1474) and in situations where the results are likely to affect medical management (p. 1475).

Egger SE, Rumble RB, Armstrong AJ, et al. Molecular biomarkers in localized prostate cancer: ASCO Guideline. J Clin Oncol. 2020;38(13):1474-1494. doi:10.1200/JCO.19.02768