PROSTATE CANCER TREATMENT AND PROGNOSTIC ALGORITHMIC TESTS

- I. The use of a prostate cancer treatment and prognostic algorithmic test (i.e., Oncotype DX Prostate (0047U), Prolaris (81541), Decipher (81542), ArteraAI (0376U)) is considered **medically necessary** when:
 - A. The member has a life expectancy of 10 years or more, AND
 - B. The member does **not** have either of the following:
 - 1. Very low-risk prostate cancer, **OR**
 - 2. Very high-risk prostate cancer.
- II. The use of the prostate cancer treatment and prognostic algorithmic test Decipher assay (81542) is considered **medically necessary** when:
 - A. The member has a life expectancy of more than 5 years, AND
 - B. The patient has had radical prostatectomy, AND
 - C. There are no lymph node metastases, AND
 - D. There is PSA persistence/recurrence.
- III. The use of a prostate cancer treatment and prognostic algorithmic test (0047U, 0376U, 81541, 81542) is considered **investigational** for all other indications.

DEFINITIONS

1. **PSA persistence/recurrence:** Defined in the NCCN Prostate Cancer guidelines (4.2024) as failure of PSA to fall to undetectable levels (PSA persistence) or undetectable PSA after a radical prostatectomy with a subsequent detectable



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PSA that increases on 2 or more determinations (PSA recurrence) or that increases to PSA greater than 0.1 ng/mL (p. PROS-10)

- 2. **Very high-risk prostate cancer:** Defined by NCCN as an individual who has no very-high-risk features but has at least <u>one</u> of the following high-risk features:
 - a. cT3b-cT4
 - b. Primary Gleason pattern 5
 - c. 2 or 3 high-risk features
 - d. More than 4 cores with Grade Group 4 or 5
- 3. Very low risk prostate cancer: Defined by NCCN as all of the following:
 - a. cT1c
 - b. Grade Group 1
 - c. PSA <10 mg/nl and density <0.15 ng/mL/g
 - d. Biopsy shows <3 positive cores/fragments and < or equal to 50% cancer in each core/fragment.

REFERENCES

- 1. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 4.2024. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
- Eggener 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

