

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)) is considered **medically necessary** when:
 - A. The member has a life expectancy of 10 years or more, **AND**
 - B. The member has any of the following:
 1. Low-risk prostate cancer, **OR**
 2. Favorable intermediate prostate cancer, **OR**
 3. Unfavorable intermediate prostate cancer, **OR**
 4. 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. For initial risk stratification, the member meets the following:
 1. The member has a life expectancy of 10 years or more, **AND**
 2. The member has any of the following:
 - a) Low-risk prostate cancer, **OR**
 - b) Favorable intermediate prostate cancer, **OR**
 - c) Unfavorable intermediate prostate cancer, **OR**
 - d) High-risk prostate cancer, **OR**
 - B. The member meets the following:
 1. The member has a life expectancy of more than 5 years, **AND**
 2. The test is being used to inform adjuvant treatment and counseling for risk stratification, as an alternative to PSADT, **OR**

3. Adverse features were found post-radical prostatectomy, including but not limited to PSA persistence/recurrence.
- III. The use of a prostate cancer treatment and prognostic algorithmic test (0047U, 81541, 81542) is considered **investigational** for all other indications.

NOTES AND DEFINITIONS

1. **Prostate cancer pathology risk stratification** is described in detail in the NCCN Prostate Cancer 1.2023 guidelines (p. PROS-2).
2. **PSA persistence/recurrence** is defined in the NCCN Prostate Cancer guidelines (1.2023) as failure of PSA to fall to undetectable levels (PSA persistence) or undetectable PSA after RP with a subsequent detectable PSA that increases on 2 or more determinations (PSA recurrence) or that increases to PSA greater than 0.1 ng/mL (p. PROS-10)
3. **Adverse pathologic features** are discussed in the NCCN Prostate Cancer guidelines (1.2023), and examples of this included positive margins, seminal vesicle invasion, and extracapsular extension. (p. MS-38)

REFERENCES

1. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 3.2023. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
2. 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