

## Evidence-Based Prostate Cancer Risk Assessment and Diagnostic Algorithmic Tests

- I. Prostate cancer risk assessment and diagnostic algorithmic tests with sufficient evidence of clinical validity and utility are considered **medically necessary** when:
  - A. The member meets all of the following:
    1. The member has not had a prostate biopsy, **AND**
    2. The member has at least one of the following:
      - a) Prostate specific antigen (PSA) greater than 3 ng/ml, **OR**
      - b) A digital rectal exam (DRE) that is suspicious for cancer, **AND**
    3. The test is one of the following:
      - a) Prostate Health Index (PHI), **OR**
      - b) SelectMDx, **OR**
      - c) 4Kscore, **OR**
      - d) ExoDx Prostate Test, **OR**
      - e) MyProstateScore 2.0 (MPS2), **OR**
      - f) IsoPSA, **OR**
  - B. The member meets all of the following:
    1. The member has had a prostate biopsy, **AND**
    2. The result is one of the following:
      - a) Atypia, suspicious for cancer, **OR**
      - b) High-grade prostatic intraepithelial neoplasia (PIN), **OR**
      - c) Benign, **AND**

3. The test is one of the following:
  - a) Prostate Health Index (PHI), **OR**
  - b) 4Kscore, **OR**
  - c) ExoDx Prostate Test, **OR**
  - d) MyProstateScore 2.0 (MPS2), **OR**
  - e) IsoPSA, **OR**
  - f) ConfirmMDx, **OR**
  - g) PCA3.
- II. The use of prostate cancer risk assessment and diagnostic algorithmic tests with sufficient evidence of clinical validity and utility are considered **investigational** for all other indications where clinical validity and utility have not been demonstrated.

## REFERENCES

1. Wei JT, Barocas D, Carlsson S, et al. Early detection of prostate cancer: AUA/SUO guideline: prostate cancer screening. J Urol. 2023;210(1):45-63.
2. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection. Version 2.2024. [https://www.nccn.org/professionals/physician\\_gls/pdf/prostate\\_detection.pdf](https://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf)