



Clinical Protocol: Diagnostics and Screenings

SUBDEPARTMENT: N/A

POLICY NO.

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TITLE OF POLICY: Prostate Cancer Early Detection

## PROTOCOL OVERVIEW

This Clinical Protocol advises on guidelines and indications for referral for Prostate Specific Antigen (PSA) Testing.

## PURPOSE

1. Prostate Specific Antigen (PSA)
  - A protein normally produced by cells of the prostate gland and measured in a routine blood test
  - Normally present at low levels in the bloodstream
  - May increase as a result of either prostate cancer or benign conditions, most commonly prostatitis and benign prostatic hyperplasia
  - PSA alone is not sufficient to distinguish between benign prostate conditions and cancer
  - FDA approved PSA test along with a digital rectal exam to help detect prostate cancer in men 50 years of age or older
  - FDA also approved PSA test to monitor patients with a history of prostate cancer, as a rising PSA level may signal recurrence
2. PSA Screening Indications
  - Although Medicare covers PSA testing for all men aged 50 and over once every 12 months, screening recommendations vary. The American Cancer Society recommends that men have a chance to make an informed decision with their health care provider about whether to be screened for prostate cancer. ACS recommends discussion to occur at age 50 for men at average risk of prostate cancer and expected to live at least 10 years, at age 45 for men at higher risk and at age 40 for men at highest risk (those with more than one first degree relative who had prostate cancer at an early age)
  - Risk factors for prostate cancer are:
    - Age
    - Family history (in first-degree relative)
    - Race (African American highest and Asian and Native American lowest risk)
    - Possibly, high fat diet
3. Indications for Referral
  - There is no specific “normal” or “abnormal” PSA level, although generally the higher a man’s PSA level, the more likely it is that cancer may be present.
  - A rising PSA level over time is often the indication for further testing, but there is no clear consensus on the optimal PSA threshold for recommending a prostate biopsy

- Transrectal ultrasound is commonly used to image the prostate, often as a tool during biopsy
- 65-75% of elevated PSA levels are “false positives”, meaning no cancer is found on biopsy
- PSA levels can also be “false negatives”, meaning normal tests in the presence of cancer
- Rising PSA level after treatment for prostate cancer - The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines state additional treatment may be indicated based on the following PSA test results:
  - A doubling of PSA level in fewer than 3 years while in the “watchful waiting” phase, or a PSA velocity of greater than 0.75 ng/mL per year, or biopsy showing worsening cancer
  - If PSA does not fall below the limits of detection after radical prostatectomy, or if PSA level increases on two or more measurements after having no detectable PSA
  - A PSA level that has risen by 2 ng/mL or more after having no detectable PSA following other therapy such as radiation therapy
- A man should discuss a rising PSA level with his doctor, as additional treatment based on a single PSA test result is often not recommended

## CITATIONS

American Cancer Society (2023). American Cancer Society Recommendations for Prostate Cancer Early Detection. <https://www.cancer.org/cancer/types/prostate-cancer/detection-diagnosis-staging/acsrecommendations.html>

National Cancer Institute (2022). Prostate-Specific Antigen (PSA) Test. <https://www.cancer.gov/types/prostate/psa-fact-sheet>