

**Subject:** Prostate Specific Antigen Testing  
**Guideline #:** CG-LAB-28  
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## Description

This document addresses the use of laboratory testing for prostate specific antigen (PSA) levels. Low levels of serum total PSA are normal, higher levels of serum PSA may indicate a malignancy. PSA testing is considered a relatively non-specific tool as elevated PSA levels may also have benign causes.

**Note:** This document does not address the use of following PSA laboratory tests:

- Complexed PSA
- Free PSA
- Prostate Health Index (PHI)

## Clinical Indications

### Medically Necessary:

Prostate specific antigen (PSA) testing is considered **medically necessary** for any of the following indications:

- Screening for prostate cancer;**or**
- Evaluation of signs or symptoms suggestive of prostate cancer;**or**
- Individuals with previous elevated or rising PSA levels;**or**
- Individuals with current or past history of prostate cancer.

### Not Medically Necessary:

PSA testing is considered **not medically necessary** for all other indications not listed above.

## Coding

*The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.*

### When services are Medically Necessary:

#### CPT

84153 Prostate specific antigen (PSA); total

#### HCPCS

G0103 Prostate cancer screening; prostate specific antigen test (PSA)

#### ICD-10 Diagnosis

C61	Malignant neoplasm of prostate
C67.0-C67.9	Malignant neoplasm of bladder
C77.4-C77.5	Secondary and unspecified malignant neoplasm of inguinal and lower limb or intrapelvic lymph nodes
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
C79.51-C79.52	Secondary malignant neoplasm of bone, bone marrow
C79.82	Secondary malignant neoplasm of genital organs
D07.5	Carcinoma in situ of prostate
D40.0	Neoplasm of uncertain behavior of prostate
D49.511-D49.519	Neoplasm of unspecified behavior of kidney
D49.59	Neoplasm of unspecified behavior of other genitourinary organs
M33.03	Juvenile dermatomyositis without myopathy
M33.13	Other dermatomyositis without myopathy
M33.93	Dermatopolymyositis, unspecified without myopathy
N13.8-N13.9	Other/unspecified obstructive and reflux uropathy
N32.0	Bladder-neck obstruction
N40.0-N40.3	Benign prostatic hyperplasia
N41.8-N41.9	Other/unspecified inflammatory diseases of prostate
N42.30-N42.39	Dysplasia of prostate
N42.9	Disorder of prostate, unspecified
R31.0-R31.9	Hematuria
R32	Unspecified urinary incontinence
R33.8-R33.9	Other/unspecified retention of urine
R35.0-R35.89	Polyuria
R39.11-R39.198	Other difficulties with micturition
R93.5-R93.7	Abnormal findings on diagnostic imaging of other abdominal regions, including retroperitoneum, limbs, or other parts of musculoskeletal system
R94.8	Abnormal results of function studies of other organs and systems

R97.20-R97.21	Elevated prostate specific antigen [PSA]
Z00.00-Z00.01	Encounter for general adult medical examination
Z12.5	Encounter for screening for malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

#### When services are Not Medically Necessary:

For the procedure codes listed above for all other diagnoses.

### Discussion/General Information

Prostate cancer is one of the most common types of cancer with approximately 268,490 new cases diagnosed and 34,500 deaths estimated in 2022. More than half of the cases are diagnosed in individuals aged 65 or older. (American Cancer Society [ACS], 2022). PSA is a glycoprotein which is normally concentrated in the prostate tissue, but detectable levels are also found in blood. An elevated PSA may be an early sign of prostate cancer, PSA is considered a highly sensitive, but poorly specific test. An elevated PSA is a sign of prostate pathology but is not specific to prostate cancer. Prostatitis, benign prostatic hyperplasia (BPH) or prostate infection are examples of benign conditions which may be associated with an elevated PSA (NCI, 2022).

In 1986 the Food and Drug Administration (FDA) approved the first PSA test to be used to monitor disease progression in individuals already diagnosed with prostate cancer. The FDA expanded the approved indications for the PSA test to be used in conjunction with a digital rectal exam (DRE) as a screening test in individuals aged 50 and older.

#### Screening

Asymptomatic individuals aged 55 to 69 years old may decide to undergo prostate cancer screening after discussing the risk and potential harms associated with screening with their healthcare provider. Prostate cancer screening using PSA testing has the potential to reduce prostate specific mortality. PSA testing could result in overdiagnosis and overtreatment and lead to conditions which may adversely affect quality of life including increased stress levels, incontinence and erectile dysfunction.

Using retrospective data from 128 US Veterans Health Administration (VHA) facilities, Bryant and colleagues (2022) assessed whether variation in PSA screening rates is associated with subsequent metastatic prostate cancer incidence. Between 2005 and 2019, counts of individuals undergoing PSA screening, prostate biopsies and incidence of prostate cancer cases were calculated yearly and grouped by age. The PSA screening rate at a facility was calculated by dividing the number of individuals aged 40 or older who underwent PSA screening by the total number of individuals who received any care at the facility who would have been eligible for PSA screening test. In 2005, the eligible VHA population included 4,678,412 individuals. In 2008, the overall screening rate rose to a high of 50.8% from the 2005 baseline of 47.2%. In 2019, the overall screening rate decreased to 37.0%. This decrease was reported across all age groups. The long-term results showed that higher yearly metastatic prostate cancer incidence rates beginning 2010 through 2019 was associated with lower facility-level screening rates 5 years earlier. Data comparing long-term non-screening rates and incidence of metastatic prostate cancer report similar results. The authors suggest that the study conclusions be used to inform individuals within the context of the current United States Preventive Services Task Force (USPSTF) shared decision making model noting:

Our results also do not directly implicate changes in USPSTF recommendations or the publication of PSA screening trial results to the absolute increase in metastatic prostate cancer incidence since 2012, and the magnitude of our observed incidence rate ratios are not consistent with changes in PSA screening patterns being the sole factor associated with the increase in metastatic prostate cancer incidence.

In 2023, the American Urological Association (AUA) and the Society of Urologic Oncology (SUO) published a guideline on prostate cancer screening which includes the following recommendations:

1. Clinicians should engage in shared decision-making (SDM) with people for whom prostate cancer screening would be appropriate and proceed based on a person's values and preferences. (Clinical Principle)
2. When screening for prostate cancer, clinicians should use PSA as the first screening test. (Strong Recommendation; Evidence Level: Grade A)
3. For people with a newly elevated PSA, clinicians should repeat the PSA prior to a secondary biomarker, imaging, or biopsy. (Expert Opinion)
4. Clinicians may begin prostate cancer screening and offer a baseline PSA test to people between ages 45 to 50 years. (Conditional Recommendation; Evidence Level: Grade B)
5. Clinicians should offer prostate cancer screening beginning at age 40 to 45 years for people at increased risk of developing prostate cancer based on the following factors: Black ancestry, germline mutations, strong family history of prostate cancer. (Strong Recommendation; Evidence Level: Grade B)
6. Clinicians should offer regular prostate cancer screening every 2 to 4 years to people aged 50 to 69 years. (Strong Recommendation; Evidence Level: Grade A)
7. Clinicians may personalize the re-screening interval, or decide to discontinue screening, based on patient preference, age, PSA, prostate cancer risk, life expectancy, and general health following SDM. (Conditional Recommendation; Evidence Level: Grade B)
8. Clinicians may use digital rectal exam (DRE) alongside PSA to establish risk of clinically significant prostate cancer. (Conditional Recommendation; Evidence Level: Grade C)
9. For people undergoing prostate cancer screening, clinicians should not use PSA velocity as the sole indication for a secondary biomarker, imaging, or biopsy. (Strong Recommendation; Evidence Level: Grade B)

The USPSTF gives the recommendation that asymptomatic individuals aged 55 to 69 years old undergo periodic testing a grade "C" (no recommendation for or against routine provision of the service). The National Comprehensive Cancer Network (NCCN) clinical practice guideline on the early detection of prostate cancer considers PSA testing an early detection technique which has demonstrated survival benefits, particular when used in combination with digital rectal examination or other ancillary testing (V2.2023)

#### Signs or symptoms suggestive of prostate cancer

The early stages of prostate cancer are typically asymptomatic. In more advanced stages, genitourinary symptoms may be present including problems with urination, blood in urine or semen or erectile dysfunction (ACS, 2022). Prostate cancer can also manifest as lower extremity weakness or paresthesia or loss of bladder or bowel control due to tumor impinging on the spinal cord (ACS, 2022). Bony metastatic disease to the axis skeleton is common and may cause back pain (Rawla, 2019). PSA levels, along with other clinical and pathologic features, are used in the initial risk stratification and staging workup of prostate cancer. Individuals with an initial PSA < 10 ng/mL are considered very low risk group for cancer recurrence and prostate cancer specific mortality while a PSA > 20 ng/mL indicates high-risk for cancer recurrence and prostate cancer specific mortality. The PSA level prior to treatment predicts tumor response to local therapy and prostate cancer-specific and overall mortality (AUA, 2013). The AUA and the American Society for

Radiation Oncology (ASTRO) guideline for clinically localized prostate cancer (2022) includes the following recommendation:

Clinicians should use clinical T stage, serum prostate-specific antigen (PSA), Grade Group (Gleason score), and tumor volume on biopsy to risk stratify patients with newly diagnosed prostate cancer. (Strong Recommendation; Evidence Level: Grade A)

The most common sites of prostate metastasis include bones, lymph nodes, lungs and liver. The NCCN recommends workup for potential metastasis include PSA testing (NCCN, 4.2023).

PSA testing may be indicated in individuals with primary non-prostate cancers. This testing may be part of the initial workup or during disease management. In advanced disease in adjacent organs, such as bladder cancer, the tumor may invade the prostate. The NCCN CPG for bladder cancer (V3.2023) recommends PSA testing in cases of suspected urothelial carcinoma of the prostate. An estimated 24-51% of individuals with muscle invasive bladder cancer are shown to have incidental prostate cancer (Lopez-Beltran, 2017). The NCCN recommends periodic screening for secondary primary cancers be utilized following treatment during the surveillance period (Colon, V2.2022; NCCN, Hodgkin V1.2024)

### **Monitoring**

#### *Active Surveillance (AS) also known as Active Monitoring*

Prostate cancer can be characterized as aggressive or indolent. Individuals at low risk for aggressive cancer, such as those with localized prostate cancer, may be candidates for active surveillance (AS) or definitive treatment. The concept of AS is to potentially avoid or delay the negative side effects of prostate cancer therapy. The United States Preventive Services Task Force (USPSTF) notes:

"Early, active treatment for screen-detected prostate cancer may reduce the risk of metastatic disease, although the long-term impact of early, active treatment on prostate cancer mortality remains unclear. Active treatments for prostate cancer are frequently associated with sexual and urinary difficulties."

The AS protocol involves actively monitoring the course of prostate cancer with the intent to initiate curative treatment if the cancer progresses (NCCN, V1.2024). ASCO recommends PSA testing every 3 to 6 months (Chen, 2016). Other societies recommend PSA rechecks no more often than every 6 months in AS, unless clinically indicated (NCCN, V1.2024; Eastham, 2015). During AS, an increase in a PSA level should trigger a PSA retest, as transient increases are not unusual (Eastham, 2015). A 2020 Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review on clinically localized prostate cancer notes:

Active monitoring [AM] using PSA-based monitoring probably results in little to no difference in all-cause or prostate cancer mortality compared with RP [radical prostatectomy] or EBR [external beam radiation] plus AD [androgen deprivation] over 10 years. Metastases were infrequent, but AM probably results in a small increase compared with RP and EBR+AD. Effects may not vary by patient or tumor risk factors. Harms were lowest with AM compared with RP or EBR plus AD or AS versus photodynamic therapy.

#### *Monitoring During Therapy*

PSA levels are indicative of treatment response. An increase in PSA by 2 ng/mL above the nadir following radiation therapy with or without hormone treatment is the standard definition of disease recurrence. The PSA nadir following treatment is also a prognostic factor (Shah, 2016). A PSA rise following local therapy may aid in distinguishing between a local and distant recurrence (AUA, 2013).

PSA levels are monitored during treatment as levels may guideline treatment decisions. The AUA/ASTRO guideline for clinically localized prostate cancer (2022) includes the following recommendations:

Clinicians should risk stratify patients with positive lymph nodes identified at radical prostatectomy based on pathologic variables and postoperative PSA. (Expert Opinion)

Clinicians may offer patients with positive lymph nodes identified at radical prostatectomy and an undetectable postoperative PSA adjuvant therapy or observation. (Conditional Recommendation; Evidence Level: Grade C)

Clinicians should monitor patients with prostate cancer post therapy with PSA and symptom assessment. (Clinical Principle)

#### *Recurrence Surveillance*

Following prostate cancer treatment, PSA levels should be checked every 6 -12 months for the first 5 years to detect cancer recurrence. Following the first 5 years, an annual PSA level measurement is recommended. Some individuals may require more frequent PSA monitoring based upon individual risk factors for recurrence and specific circumstances (Resnick, 2015).

There are several disease states associated with advanced prostate cancer. Biochemical recurrence is typically the first sign of prostate cancer recurrence and almost always precedes the clinical detection of metastases. Hormone-sensitive or castration-resistant prostate cancer are defined by individual response to androgen deprivation therapy (ADT) therapy. These individuals are typically followed with serial PSA testing and clinical evaluations to follow disease progression (AUA/ASTRO/SGO, 2020). PSA doubling-time (PSADT) along with time to PSA recurrence following therapy is considered a prognostic factor in individuals who experience clinical recurrence.

The 2023 AUA/ SUO guidelines on advanced prostate cancer recommend PSA measurements to monitor treatment in the following conditions:

#### Biochemical Recurrence Without Metastatic Disease After Exhaustion of Local Treatment Options

##### Prognosis

4. Clinicians should inform patients with PSA recurrence after exhaustion of local therapy regarding the risk of developing metastatic disease and follow such patients with serial PSA measurements and clinical evaluation. Clinicians may consider radiographic assessments based on overall PSA and PSA kinetics. (Clinical Principle)

#### Metastatic Hormone-Sensitive Prostate Cancer (mHSPC)

##### Prognosis

12. Clinicians should obtain a baseline PSA and serial PSAs at three- to six-month intervals after initiation of ADT in mHSPC patients and consider periodic conventional imaging. (Clinical Principle)

#### Non-Metastatic Castration-Resistant Prostate Cancer (nmCRPC)

##### Prognosis

20. In nmCRPC patients, clinicians should obtain serial PSA measurements at three- to six-month intervals, and

calculate a PSADT starting at the time of development of castration-resistance. (Clinical Principle)

#### Metastatic Castration-Resistant Prostate Cancer (mCRPC)

##### Prognosis

25. In mCRPC patients, clinicians should obtain baseline labs (e.g., PSA, testosterone, LDH, Hgb, alkaline phosphatase level) and review location of metastatic disease (lymph node, bone, visceral), disease-related symptoms, and performance status to inform discussions of prognosis and treatment decision-making. (Clinical Principle)

#### *Dermatomyositis*

Dermatomyositis is a rare idiopathic systematic inflammatory autoimmune disease. Individuals with dermatomyositis have an approximately fivefold increased risk of developing cancer (Olazagasti, 2015; Qiang, 2017). The exact underlying connection between dermatomyositis and cancer is unknown but has been proposed to be due to crossover immunity. Individuals with dermatomyositis are encouraged to undergo conventional cancer screening with a comprehensive history and physical, laboratory and imaging testing and tumor markers including PSA testing in the appropriate population (Olazagasti, 2015; Oldroyd, 2021; Udkoff, 2016).

### Definitions

**Biochemical Recurrence:** Rising PSA levels in individuals with prostate cancer post-treatment (surgery or radiation), with or without symptoms. The increase in the PSA level may indicate the cancer has returned. Also called biochemical relapse or PSA failure.

**Indolent Cancer:** A slow growing type of cancer which may be inconsequential and may not become symptomatic to the affected individual or contribute to death.

**PSA Doubling Time (PSADT):** The number of months needed for the PSA value to increase 2-fold.

**PSA nadir:** The lowest PSA level reached following radiation therapy to treat prostate cancer.

**Urothelial Cancer:** Cancer which develops in the cells lining the urethra, bladder, ureters, renal pelvis or prostate. Also called transitional cell cancer.

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## Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

## History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Description, Discussion and References sections.
	12/06/2023	Revised References section.
New	02/16/2023	MPTAC review. Initial document development.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical

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