

If a conflict arises between a Clinical Payment and Coding Policy and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. "Plan documents" include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. Blue Cross and Blue Shield of TX may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. Blue Cross and Blue Shield of TX has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing Editor, American Medical Association, Current Procedural Terminology, CPT® Assistant, Healthcare Common Procedure Coding System, ICD-10 CM and PCS, National Drug Codes, Diagnosis Related Group guidelines, Centers for Medicare and Medicaid Services National Correct Coding Initiative Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

Prostate Specific Antigen (PSA) Testing

Policy Number: CPCPLAB006

Version 1.0

Approval Date: Sept. 13, 2024

Plan Effective Date: Jan. 1, 2025 (Blue Cross and Blue Shield of Texas Only)



Description

The plan has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

Reimbursement Information:

- 1. For average-risk individuals 45-75 years of age, screening for prostate cancer with the total prostate-specific antigen (PSA) test **may be reimbursable.**
- 2. For individuals 40-75 years of age, annual screening for prostate cancer with the total prostate-specific antigen (PSA) test **may be reimbursable** when one of the following conditions is met:
 - a. Individual is of African ancestry;
 - b. Individual has germline mutations that increase risk for prostate cancer;
 - c. Individual has a suspicious family history.
- 3. For individuals over 75 years of age who have little or no comorbidities (See **Note 1**), screening for prostate cancer with a total PSA test **may be reimbursable.**
- 4. For individuals with previous total PSA results, repeat screening for prostate cancer with a total PSA test **may be reimbursable** with the following frequency:
 - For individuals less than 76 years of age when total PSA is <1 ng/ml and digital rectal exam (DRE) is normal (if done): Repeat screening at 2-4 year intervals;
 - b. For individuals less than 76 years of age when total PSA is 1-3 ng/ml and DRE is normal (if done): Repeat screening at 1-2 year intervals;
 - c. For individuals greater than 75 years of age when total PSA is <4 ng/ml and DRE is normal (if done) and no other indications for biopsy: Repeat screening in select patients (very healthy individuals with little or no comorbidity) at 1-4 year intervals.
- 5. TRUS-guided biopsy, percent free PSA, or a follow-up in 6-12 months with total PSA or DRE **may be reimbursable** when any of the following conditions are met:
 - a. For individuals less than 76 years of age with a total PSA >3 ng/ml and/or a very suspicious DRE;
 - b. For select individuals greater than 75 years of age (very healthy individuals with little or no comorbidity) with a total PSA >4 ng/ml or a very suspicious DRE.
- 6. For individuals thought to be at a higher risk despite at least one prior negative prostate biopsy, follow-up testing with percent free PSA **may be reimbursable**.



- 7. Total PSA testing **may be reimbursable** in any of the following situations:
 - a. For initial prostate cancer diagnosis in individuals with signs and symptoms of prostate cancer (See **Note 2**);
 - b. For follow-up of individuals with a current or previous diagnosis of prostate cancer;
 - c. For ongoing monitoring of individuals who have undergone tumor resection or prostatectomy;
 - d. For monitoring response to therapy;
 - e. For detecting disease recurrence.
- 8. Testing in the following situations **is not reimbursable**:
 - Percent free PSA as a first-line screening test for prostate cancer; OR
 - Percent free PSA, free-to-total PSA ratio, and/or complexed PSA tests for the routine screening of prostate cancer.

NOTE 1: According to the NCCN guidelines, "Testing after 75 years of age should be done only in very healthy men with little or no comorbidity (especially if they have never undergone PSA testing or have a rising PSA) to detect the small number of aggressive cancers that pose a significant risk if left undetected until signs or symptoms develop. Widespread screening in this population would substantially increase rates of over detection and is not recommended (NCCN, 2023b)." Additionally, the term individuals in this policy applies to individuals who have a prostate or were born with a prostate.

NOTE 2: According to ACS, 2019: "Most prostate cancers are found early, through screening. Early prostate cancer usually causes no symptoms. More advanced prostate cancers can sometimes cause symptoms, such as:

- Problems urinating, including a slow or weak urinary stream or the need to urinate more often, especially at night
- Blood in the urine or semen
- Trouble getting an erection (erectile dysfunction or ED)
- Pain in the hips, back (spine), chest (ribs), or other areas from cancer that has spread to bones
- Weakness or numbness in the legs or feet, or even loss of bladder or bowel control from cancer pressing on the spinal cord (ACS, 2019)."

Procedure Codes

The following is not an all-encompassing code list. The inclusion of a code does not guarantee it is a covered service or eligible for reimbursement.

Codes

84152, 84153, 84154, G0103



References:

AACU. (2018). *Genomic testing in prostate cancer*. https://aacuweb.org/wp-content/uploads/2022/02/Position-Statement-Tissue-based-genetic-testing-in-prostate-cancer-Endorsement-02-26-18.pdf

AAFP. (2018a). *American Academy of Family Physicians*. http://www.choosingwisely.org/clinician-lists/american-academy-family-physicians-prostate-cancer-psa-test/

AAFP. (2018b). Counseling Patients About Prostate Cancer Screening. *Am Fam Physician*, *98*(8), 478-483. https://www.aafp.org/afp/2018/1015/p478.html

ACS. (2019). *Signs and Symptoms of Prostate Cancer*. https://www.cancer.org/cancer/prostate-cancer/detection-diagnosis-staging/signs-symptoms.html

ACS. (2021). *American Cancer Society Recommendations for Prostate Cancer Early Detection* https://www.cancer.org/cancer/prostate-cancer/detection-diagnosis-staging/acs-recommendations.html

ACS. (2022). *Survival Rates for Prostate Cancer*. https://www.cancer.org/cancer/prostate-cancer/detection-diagnosis-staging/survival-rates.html

Ahlering, T., Huynh, L. M., Kaler, K. S., Williams, S., Osann, K., Joseph, J., Lee, D., Davis, J. W., Abaza, R., Kaouk, J., Patel, V., Kim, I. Y., Porter, J., & Hu, J. C. (2019). Unintended consequences of decreased PSA-based prostate cancer screening. *World J Urol*, *37*(3), 489-496. https://doi.org/10.1007/s00345-018-2407-3

American_Cancer_Society. (2023). Key Statistics for Prostate Cancer. https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html#:~:text=The%20American%20Cancer%20Society's%20estimates,33%2C330%20deaths%20from%20prostate%20cancer

Balducci, L., Pow-Sang, J., Friedland, J., & Diaz, J. I. (1997). Prostate cancer. *Clin Geriatr Med*, *13*(2), 283-306. https://pubmed.ncbi.nlm.nih.gov/9115452/

Baniak, N., Sholl, L. M., Mata, D. A., D'Amico, A. V., Hirsch, M. S., & Acosta, A. M. (2020). Clinicopathologic and Molecular Characteristics of Prostate Cancer Diagnosed in Young Men Aged up to 45 Years. *Histopathology*. https://doi.org/10.1111/his.14315

Bell, K. J., Del Mar, C., Wright, G., Dickinson, J., & Glasziou, P. (2015). Prevalence of incidental prostate cancer: A systematic review of autopsy studies. *Int J Cancer*, *137*(7), 1749-1757. https://doi.org/10.1002/ijc.29538



Brawley, S., Mohan, R., & Nein, C. (2018). Localized Prostate Cancer: Treatment Options. *American Family Physician*, *97*(12), 798-805. https://www.aafp.org/pubs/afp/issues/2018/0615/p798.html

Carter, H. B., Albertsen, P. C., Barry, M. J., Etzioni, R., Freedland, S. J., Greene, K. L., Holmberg, L., Kantoff, P., Konety, B. R., Murad, M. H., Penson, D. F., & Zietman, A. L. (2013). Early detection of prostate cancer: AUA Guideline. *J Urol*, *190*(2), 419-426. https://doi.org/10.1016/j.juro.2013.04.119

CDC. (2022a). *Leading Cancer Cases and Deaths, Male, 2019*. https://gis.cdc.gov/Cancer/USCS/DataViz.html

CDC. (2022b). *Should I Get Screened for Prostate Cancer?* Retrieved 12/30/2020 from https://www.cdc.gov/cancer/prostate/basic_info/get-screened.htm

Center, M. S. K. C. (2022). *Prostate Cancer Screening Guidelines*. https://www.mskcc.org/cancer-care/types/prostate/screening/screening-guidelines-prostate

Chang, S. L., Harshman, L. C., & Presti, J. C., Jr. (2010). Impact of common medications on serum total prostate-specific antigen levels: analysis of the National Health and Nutrition Examination Survey. *J Clin Oncol*, *28*(25), 3951-3957. https://doi.org/10.1200/jco.2009.27.9406

Coban, S., Doluoglu, O. G., Keles, I., Demirci, H., Turkoglu, A. R., Guzelsoy, M., Karalar, M., & Demirbas, M. (2016). Age and total and free prostate-specific antigen levels for predicting prostate volume in patients with benign prostatic hyperplasia. *Aging Male*, *19*(2), 124-127. https://doi.org/10.3109/13685538.2015.1131260

FDA. (2012). ACCESS HYBRITECH P2PSA ON THE ACCESS IMMUNOASSAY SYSTEMS. https://www.accessdata.fda.gov/cdrh_docs/pdf9/P090026B.pdf

FDA. (2023). *TANDEM-R PSA IMMUNORADIOMETRIC ASSAY*. https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pma&id=3 19006

Fisher, K. W., Montironi, R., Lopez Beltran, A., Moch, H., Wang, L., Scarpelli, M., Williamson, S. R., Koch, M. O., & Cheng, L. (2015). Molecular foundations for personalized therapy in prostate cancer. *Curr Drug Targets*, *16*(2), 103-114. https://doi.org/10.2174/1389450115666141229154500

Fleshner, K., Carlsson, S. V., & Roobol, M. J. (2017). The effect of the USPSTF PSA screening recommendation on prostate cancer incidence patterns in the USA. *Nat Rev Urol*, *14*(1), 26-37. https://doi.org/10.1038/nrurol.2016.251



Freedland, S. (2022). *Measurement of prostate-specific antigen*. Wolters Kluwer. Retrieved 1/19/21 from https://www.uptodate.com/contents/measurement-of-prostate-specific-

antigen?search=prostate%20specific%20antigen&source=search_result&selectedTitle=1~130&usage_type=default&display_rank=1

Hamilton, R. J., Goldberg, K. C., Platz, E. A., & Freedland, S. J. (2008). The influence of statin medications on prostate-specific antigen levels. *J Natl Cancer Inst*, 100(21), 1511-1518. https://doi.org/10.1093/jnci/djn362

Hoffman, R. (2023). *Screening for prostate cancer - UpToDate* https://www.uptodate.com/contents/screening-for-prostate-cancer?source=see_link#H30

Ilic, D., Djulbegovic, M., Jung, J. H., Hwang, E. C., Zhou, Q., Cleves, A., Agoritsas, T., & Dahm, P. (2018). Prostate cancer screening with prostate-specific antigen (PSA) test: a systematic review and meta-analysis. *Bmj*, *362*, k3519. https://doi.org/10.1136/bmj.k3519

Magnani, C. J., Bievre, N., Baker, L. C., Brooks, J. D., Blayney, D. W., & Hernandez-Boussard, T. (2021). Real-world Evidence to Estimate Prostate Cancer Costs for First-line Treatment or Active Surveillance. *Eur Urol Open Sci*, *23*, 20-29. https://doi.org/10.1016/j.euros.2020.11.004

Martin, R. M., Donovan, J. L., Turner, E. L., Metcalfe, C., Young, G. J., Walsh, E. I., Lane, J. A., Noble, S., Oliver, S. E., Evans, S., Sterne, J. A. C., Holding, P., Ben-Shlomo, Y., Brindle, P., Williams, N. J., Hill, E. M., Ng, S. Y., Toole, J., Tazewell, M. K., . . . Hamdy, F. C. (2018). Effect of a Low-Intensity PSA-Based Screening Intervention on Prostate Cancer Mortality: The CAP Randomized Clinical Trial. *Jama*, *319*(9), 883-895. https://doi.org/10.1001/jama.2018.0154

Mottet, N., Bellmunt, J., Bolla, M., Briers, E., Cumberbatch, M. G., De Santis, M., Fossati, N., Gross, T., Henry, A. M., Joniau, S., Lam, T. B., Mason, M. D., Matveev, V. B., Moldovan, P. C., van den Bergh, R. C. N., Van den Broeck, T., van der Poel, H. G., van der Kwast, T. H., Rouviere, O., . . . Cornford, P. (2020). EAU-EANM-ESTRO-ESUR-SIOG Guidelines on ProstateCancer-2020 Update. Part 1: Screening, Diagnosis, and Local Treatment with Curative Intent. *Eur Urol*, *71*(4), 618-629. https://doi.org/10.1016/j.eururo.2016.08.003

NCCN. (2023a). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

NCCN. (2023b). *Prostate Cancer Early Detection Version 1.2023*. Retrieved 2/9/2023 from https://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf



NCI. (2022a). *Prostate-Specific Antigen (PSA) Test.* https://www.cancer.gov/types/prostate/psa-fact-sheet

NCI. (2022b). *Prostate Cancer Screening (PDQ®)–Health Professional Version*. https://www.cancer.gov/types/prostate/hp/prostate-screening-pdq#_1

Osses, D. F., Remmers, S., Schroder, F. H., van der Kwast, T., & Roobol, M. J. (2019). Results of Prostate Cancer Screening in a Unique Cohort at 19yr of Follow-up. *Eur Urol*, *75*(3), 374-377. https://doi.org/10.1016/j.eururo.2018.10.053

Parker, C., on behalf of the, E. G. C., Gillessen, S., on behalf of the, E. G. C., Heidenreich, A., on behalf of the, E. G. C., Horwich, A., & on behalf of the, E. G. C. (2020). Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. https://www.annalsofoncology.org/action/showPdf?pii=S0923-7534%2820%2939898-7

Prcic, A., Begic, E., & Hiros, M. (2016). Actual Contribution of Free to Total PSA Ratio in Prostate Diseases Differentiation. *Med Arch*, 70(4), 288-292. https://doi.org/10.5455/medarh.2016.70.288-292

Qaseem, A., Barry, M. J., Denberg, T. D., Owens, D. K., & Shekelle, P. (2013). Screening for prostate cancer: a guidance statement from the Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med*, *158*(10), 761-769. https://doi.org/10.7326/0003-4819-158-10-201305210-00633

Rodrigues, D. N., Butler, L. M., Estelles, D. L., & de Bono, J. S. (2014). Molecular pathology and prostate cancer therapeutics: from biology to bedside. *J Pathol*, *232*(2), 178-184. https://doi.org/10.1002/path.4272

Saini, S. (2016). PSA and beyond: alternative prostate cancer biomarkers. *Cell Oncol (Dordr)*, *39*(2), 97-106. https://doi.org/10.1007/s13402-016-0268-6

Singer, E. A., Palapattu, G. S., & van Wijngaarden, E. (2008). Prostate-specific antigen levels in relation to consumption of nonsteroidal anti-inflammatory drugs and acetaminophen: results from the 2001-2002 National Health and Nutrition Examination Survey. *Cancer*, *113*(8), 2053-2057. https://doi.org/10.1002/cncr.23806

Stimac, G., Spajic, B., Reljic, A., Katusic, J., Popovic, A., Grubisic, I., & Tomas, D. (2014). Effect of histological inflammation on total and free serum prostate-specific antigen values in patients without clinically detectable prostate cancer. *Korean J Urol*, *55*(8), 527-532. https://doi.org/10.4111/kju.2014.55.8.527

Tabayoyong, W., & Abouassaly, R. (2015). Prostate Cancer Screening and the Associated Controversy. *Surg Clin North Am*, *95*(5), 1023-1039. https://doi.org/10.1016/j.suc.2015.05.001



USPSTF. (2018). Draft Recommendation Statement: Prostate Cancer: Screening - US Preventive Services Task Force

https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prostate-cancer-screening

Van Poppel, H., Roobol, M. J., Chapple, C. R., Catto, J. W. F., N'Dow, J., Sønksen, J., Stenzl, A., & Wirth, M. (2021). Prostate-specific Antigen Testing as Part of a Risk-Adapted Early Detection Strategy for Prostate Cancer: European Association of Urology Position and Recommendations for 2021. *European Urology*, 80(6), 703-711. https://doi.org/10.1016/j.eururo.2021.07.024

Wang, L. G., Liu, X. M., Kreis, W., & Budman, D. R. (1997). Down-regulation of prostate-specific antigen expression by finasteride through inhibition of complex formation between androgen receptor and steroid receptor-binding consensus in the promoter of the PSA gene in LNCaP cells. *Cancer Res*, *57*(4), 714-719. https://pubmed.ncbi.nlm.nih.gov/9044850/

Wilt, T. J., Harris, R. P., & Qaseem, A. (2015). Screening for cancer: advice for high-value care from the American College of Physicians. *Ann Intern Med*, *162*(10), 718-725. https://doi.org/10.7326/m14-2326

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