

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 Oklahoma may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSOK 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 Testing

Policy Number: CPCPLAB006

Version 1.0

Approval Date: April 29, 2024

Plan Effective Date: January 15, 2025

Description

BCBSOK 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. Screening for prostate cancer with the total prostate-specific antigen/PSA test **may be reimbursable** at least once per year for men fifty (50) years or older.
- 2. Screening for prostate cancer with the total prostate-specific antigen/PSA test annually **may be reimbursable** for men aged 40-50 years who are at increased risk of developing prostate cancer as determined by a physician.
- 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:
 - a. 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. A precent free PSA **or** a follow-up in 6-12 months with total PSA **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 individuals greater than 75 years of age (very healthy individual with little or no comorbidity) with a total PSA > 4ng/ml or a very suspicious DRE.
- 6. For individual 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 prostate cancer therapy,
 - e. For detecting disease recurrence.
- 8. The following testing **is not reimbursable**:
 - a. Percent free PSA as a first-line screening test for prostate cancer; OR
 - b. 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 apply 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, 2023b)."

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). Choosing Wisely®

Prostate Cancer Screening. https://www.aafp.org/family-physician/patient-care/clinical-recommendations/all-clinical-recommendations/cw-prostate-cancer.html

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

AAFP. (2018c). Screening for Prostate Cancer: Recommendation Statement. *Am Fam Physician*, *98*(8), Online. https://www.aafp.org/pubs/afp/issues/2018/1015/od1.html

ACS. (2023a, November 22, 2023). *American Cancer Society Recommendations for Prostate Cancer Early Detection*. https://www.cancer.org/cancer/types/prostate-cancer/detection-diagnosis-staging/acs-recommendations.html

ACS. (2023b, November 22, 2023). *Signs and Symptoms of Prostate Cancer*. https://www.cancer.org/cancer/prostate-cancer/detection-diagnosis-staging/signs-symptoms.html

ACS. (2024, January 17, 2024). *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%2 0deaths%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
- 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=319006
- 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. (2024, January 23, 2024). *Measurement of prostate-specific antigen*. Wolters Kluwer. 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
- 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
- Lowrance, W. T., Breau, R. H., Chou, R., Chapin, B. F., Crispino, T., Dreicer, R., Jarrard, D. F., Kibel, A. S., Morgan, T. M., Morgans, A. K., Oh, W. K., Resnick, M. J., Zietman, A. L., & Cookson, M. S. (2021). Advanced Prostate Cancer: AUA/ASTRO/SUO Guideline PART I. *J Urol*, 205(1), 14-21. https://doi.org/10.1097/ju.000000000001375

- 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
- Memorial Sloan Kettering Cancer Center. (2022). *Prostate Cancer Screening Guidelines*. https://www.mskcc.org/cancer-care/types/prostate/screening/screening-guidelines-prostate
- 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 Version 4.2023 September 7, 2023. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
- NCCN. (2023b, January 2, 2024). *Prostate Cancer Early Detection Version 1.2024*. Retrieved 2/9/2023 from https://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf
- NCI. (2022, March 11, 2022). *Prostate-Specific Antigen (PSA) Test*. https://www.cancer.gov/types/prostate/psa-fact-sheet
- NCI. (2023, October 26, 2023). *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://pubmed.ncbi.nlm.nih.gov/27703291/
- Preston, M. A. (2023, December 5, 2023). *Screening for prostate cancer*. https://www.uptodate.com/contents/screening-for-prostate-cancer?source=see_link#H30
- 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/
- Wei, J. T., Barocas, D., Carlsson, S., Coakley, F., Eggener, S., Etzioni, R., Fine, S. W., Han, M., Kim, S. K., Kirkby, E., Konety, B. R., Miner, M., Moses, K., Nissenberg, M. G., Pinto, P. A., Salami, S. S., Souter, L., Thompson, I. M., & Lin, D. W. (2023). Early Detection of Prostate Cancer: AUA/SUO Guideline Part I: Prostate Cancer Screening. *J Urol*, 210(1), 46-53. https://doi.org/10.1097/ju.00000000000003491
- 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

Policy Update History:

Approval Date	Effective Date; Summary of Revisions
04/29/2024	01/15/2025: Document updated with literature review.
	Reimbursement information revised for clarity. Removed TRUS-
	guided biopsy and DRE from statement #5; added prostate cancer to
	#7d. References revised.
06/15/2023	06/15/2023: Document updated with literature review.
	Reimbursement information revised for clarity. References revised;
	some added, others removed.
11/1/2022	11/01/2022: New policy