

Overview of the PSA for HIM Act

Ask: PSA for HIM Act – The United States Preventive Services Task Force’s (USPSTF) current recommendation for PSA screening to detect prostate cancer does not adequately protect men who are at the highest risk for developing and dying from the disease. Because this recommendation is tied to insurance coverage, significant barriers exist for at-risk men to be screened for prostate cancer. Reps. Larry Bucshon, MD (R-IN) and Yvette Clarke (D-NY) introduced the PSA for HIM Act (H.R.1826) with original cosponsors Reps. Neal Dunn, MD (R-FL) and Troy Carter (D-LA), to ensure that screening coverage is provided to men at high risk for prostate cancer, including African-American men and men with a family history of prostate cancer or known genetic mutation, regardless of the USPSTF recommendation for these populations. We ask for your cosponsorship of H.R. 1826.

Background: The USPSTF

The United States Preventive Services Task Force (USPSTF) was created to make evidence-based recommendations for clinical preventive services and health promotion in order to aid primary care professionals, patients, and families in deciding whether a particular preventive service is the right choice for the individual’s needs. For instance, the Task Force may develop recommendations for the effectiveness of certain screening tests, counseling services, or preventive medications.

USPSTF recommendations address services offered in primary care settings, or services referred by primary care professionals, and apply only to individuals without signs or symptoms of the disease or health condition under consideration. The Director of the Agency for Healthcare Research and Quality (AHRQ), with guidance from the Chair of the Task Force, appoints the sixteen volunteer members of the Task Force, representing the fields of internal medicine, family medicine, pediatrics, behavioral health, obstetrics/gynecology, and nursing. Within the Department of Health and Human Services (HHS), AHRQ provides administrative, research, technical, and communication support to the Task Force. The Task Force is an independent body, and its work does not require AHRQ or HHS approval.

The Task Force assigns a letter grade of A, B, C, D, or I to each recommendation based on the strength of the evidence and the advantages/ disadvantages of the service under consideration:

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

For years, the medical community has referred to USPSTF recommendations to decide which preventive services to use. In some cases, insurance companies use these recommendations to decide what to cover under their policies. However, this coverage was not mandated, and decisions were left largely to providers. In 2011, the Affordable Care Act (ACA) required private insurance plans and Medicare insurance plans to cover USPSTF “A” or “B” rated preventive services without any patient cost sharing (such as copayments, co-insurance, or deductibles), removing a significant obstacle for individuals in need of preventive services. The law gives the Secretary of HHS the authority to cease Medicare coverage for a preventive service that receives a D grade from USPSTF.¹ The result of this change has been that those screening tools receiving an “A” or “B” rating from USPSTF have benefited from increased access, while other screening tools have experienced a marked decrease in access coupled with confusion over screening options. Unfortunately, many of the preventive services on which the Task Force

¹ 42 U.S.C. § 300GG-13 (<https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapXXV-partA-subpartii-sec300gg-13.pdf>)

makes recommendations, including some of the most controversial decisions, are cancer screenings, yet there were no medical oncologists consulted in the process.

The USPSTF has come under more scrutiny since its recommendations were linked to coverage decisions. The Task Force maintains that it does not conduct research, but only analyzes research to make recommendations based on a harm/benefit analysis meant for patients without obvious signs or symptoms of disease in primary care settings – i.e. routine screening for otherwise healthy patients. The Task Force also maintains that it does not make coverage decisions – those decisions are made independently by insurers and Medicare.

However, the ACA does tie Task Force decisions to mandatory coverage and cost sharing by insurers.

The USPSTF PSA Recommendation:

While screening for several diseases has benefited from an “A” or “B” rating, many USPSTF recommendations contradict leading medical opinions, including mammography for breast cancer and prostate-specific antigen (PSA) screening for prostate cancer. The current USPSTF rating for PSA screening is a “C” for men aged 55-69 and a “D” rating for men over age 70.

Many doctors and professional organizations, such as the American Urological Association (AUA), the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), the American College of Physicians-American Society of Internal Medicine, and the American Cancer Society, have encouraged yearly PSA screening for men beginning between age 40 and 55 depending on risk factors. The NCCN guidelines, which ZERO follows, recommend screening beginning at age 45. Since early-stage prostate cancer is marked by very few, if any symptoms. The PSA blood test is invaluable in its ability to alert providers to the possible presence of prostate cancer before it metastasizes into a potentially fatal diagnosis. In addition, many medical societies and patient care groups recognize that consideration of individual patient risk factors, including age, race, family history, BRCA gene mutations, and comorbidities, mean that some groups can benefit from earlier PSA screening distinct from the broader population.

After a controversial 2012 decision to give all PSA screening a “D” rating, in 2018, the USPSTF updated its recommendation for PSA screening to a “C” rating for men aged 55-69 and a “D” rating for men over age 70. The recommendation also included the following comments related to African American men and men with a family history of prostate cancer:

Within the report, the USPSTF acknowledged the following about African American men:

- “There is inadequate evidence to assess whether the benefits for African American men and men with a family history of prostate cancer aged 55 to 69 years are different than the benefits for the average-risk population. There is also inadequate evidence to assess

whether there are benefits to starting screening in these high-risk groups before age 55 years... In the United States, African American men are more likely to develop prostate cancer than white men (203.5 vs 121.9 cases per 100,000 men). African American men are also more than twice as likely as white men to die of prostate cancer (44.1 vs 19.1 deaths per 100,000 men).

- “The higher death rate is attributable in part to an earlier age at cancer onset, more advanced cancer stage at diagnosis, and higher rates of more aggressive cancer (ie, higher tumor grade).”
- “Decision analysis models suggest that given the higher rates of aggressive prostate cancer in African American men, PSA-based screening may provide greater benefit to African American men than the general population. These models also suggest a potential mortality benefit for African American men when beginning screening before age 55 years.”
- “Although the USPSTF found inadequate evidence about how benefits may differ for African American men, it recognizes the epidemiologic data showing that African American men may develop prostate cancer at younger ages than average-risk men and understands that some African American men and their clinicians will continue to screen at younger ages.”

Similarly, the USPSTF acknowledged concerns about men with a family history of prostate cancer:

- “Although the USPSTF found inadequate evidence about how benefits may differ for men with a family history of prostate cancer, it recognizes the epidemiologic data showing that these men are at a greater than average risk and understands that some men and their clinicians will continue to screen at younger ages in men with a family history.”

In addition to these statements, the USPSTF identified many areas in need of research to improve screening. The research gaps included:

- “Screening for and treatment of prostate cancer in African American men, including understanding the potential benefits and harms of different starting ages and screening intervals and the use of active surveillance; given the large disparities in prostate cancer mortality in African American men, this should be a national priority.”
- “How to better inform men with a family history of prostate cancer about the benefits and harms of PSA-based screening for prostate cancer, including the potential differences in outcomes between men with relatives who died of prostate cancer and men with relatives diagnosed with prostate cancer who died of other causes.”

In their 2018 annual report to Congress, the USPSTF issued a report to Congress that reiterated those data gaps.

Prostate cancer usually progresses relatively slowly, and the impact of the USPSTF’s decisions does not appear immediately. However, recent peer-reviewed publications have examined the results of the inadvertent experiment enacted by the USPSTF on American men in the years since 2012. In VA facilities with lower rates of prostate cancer screening in the years following the recommendation, had higher subsequent rates of metastatic prostate cancer at diagnosis.² In fact, while prior to the 2012 recommendation against prostate cancer screening, insured patients enjoyed better prostate cancer survival rates than their uninsured peers, in the years following that recommendation, the recommendation itself may have hindered prostate cancer screening among insured patients and led to worse disease outcomes in that group, while leaving outcomes in uninsured patients unchanged.³

The PSA for HIM Act:

Previously introduced in the 116th and 117th Congresses, Representatives Larry Bucshon, MD (R-IN) and Yvette Clarke (D-NY) have introduced legislation, H.R. 1826 that requires federal agencies to treat PSA screening for African-American men and men with a family history or genetic mutation for prostate cancer as if it received an “A” recommendation from the USPSTF.

Specifically, the legislation ensures that “a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible)” for prostate cancer screening for African American men and men with a family history of prostate cancer, other cancers known to be associated with an increased risk of prostate cancer, or genetic alterations known to be associated with an increased risk of prostate cancer.

This legislation has the practical effect of requiring insurance carriers to provide prostate cancer screening to these populations without a copay – making sure that men who are at the highest risk for developing lethal prostate cancer have the fewest barriers to access for screening.

The legislation is similar to the approach used by breast cancer advocates when, in 2009, the USPSTF downgraded its recommendation on mammography screening for women under 50 to a “C.” The Senate added a provision to the Affordable Care Act that made the USPSTF’s previous recommendation (a “B”) the operative rating.

² Bryant AK, Lee KM, Alba PR, et al. Association of Prostate-Specific Antigen Screening Rates With Subsequent Metastatic Prostate Cancer Incidence at US Veterans Health Administration Facilities. *JAMA Oncol.* 2022;8(12):1747–1755. doi:10.1001/jamaoncol.2022.4319

³ Kim, I.E., Kim, D.D., Kim, S. et al. Changes in prostate cancer survival among insured patients in relation to USPSTF screening recommendations. *BMC Urol* 22, 91 (2022). <https://doi.org/10.1186/s12894-022-01045-0>

The USPSTF argues that more data on at-risk populations is needed to justify changes to its screening guidelines. However, there are several barriers to the completion of such studies in the near future:

- Since prostate cancer is slow growing, a comprehensive research study would take twenty years to generate sufficient data to make a recommendation.
- Researchers have an ethical issue with screening some men and not others. Therefore, it is unlikely that researchers will conduct a study on PSA screening in African American and men with a family history.
- Even if we as a nation were willing to wait 20 years and there were researchers willing to conduct what they consider an unethical study, it is extremely difficult to enroll a sufficient number of African Americans or men with a family history in research trials.

It is time for Congress to fill the screening recommendation gap where there is clear epidemiological data to screen our men at high risk for prostate cancer.