American Urological Association

Advancing Urology™

Biomarker Testing Advocacy Toolkit

Introduction

On behalf of the American Urological Association (AUA), we support _____, legislation to ensure coverage of biomarker testing when medically appropriate for diagnosis, treatment, management, or monitoring. Biomarker testing is recognized as standard of care in leading clinical guidelines, including the National Comprehensive Cancer Network (NCCN) and American Urological Association (AUA). These guidelines recommend biomarker testing for prostate cancer patients to guide treatment decisions, improve outcomes, and ensure precision medicine approaches. Many major insurers, such as UnitedHealthcare, Aetna, and Blue Cross Blue Shield, already cover biomarker testing when medically necessary, and several states have enacted laws requiring coverage. Expanding access through legislation ensures patients receive guideline-supported care without financial barriers, aligning state policy with best practices and existing insurer standards.

Biomarker testing is a critical gateway to precision medicine, enabling targeted therapies that improve survivorship, reduce unnecessary procedures, lower costs, and enhance quality of life, particularly in prostate cancer, where combining urine tests with PSA can cut unnecessary biopsies by up to 41%. Yet access remains inequitable, with marginalized, rural, and lower-income communities less likely to benefit. Expanding coverage would help ensure that all patients receive the right treatment at the right time, reduce health disparities, and strengthen cancer care outcomes.

Principles of Biomarker testing

- **Early Detection Advantage:** Biomarker testing, like PSA screening, can detect cancer before symptoms appear, offering patients a nearly 100% five-year survival rate when caught early.[1]
- **Selective Treatment Benefits:** Biomarker testing helps distinguish aggressive cancers from low-risk cases, supporting active surveillance and reducing overtreatment risks.
- **Costs and Access Barriers:** Even small out-of-pocket costs discourage preventive care. Coverage should align with other high-value screenings such as mammograms and colonoscopies to ensure affordability.
- **System-Wide Impact:** Coverage lowers costs, reduces unnecessary procedures, and strengthens cancer care for patients and providers alike.

[1] Vickers AJ, Roobol MJ, Lilja H. Screening for prostate cancer: early detection or overdetection? Annu Rev Med. 2012;63:161-70. doi: 10.1146/annurev-med-050710-134421. Epub 2011 Nov 3. PMID: 22053739; PMCID: PMC3415315.

Background

Biomarkers are measurable indicators such as genes, proteins, or other molecules that provide critical information about normal biological processes, disease progression, or responses to therapy. Biomarker testing involves analyzing tissue, blood, or other biospecimens to detect biomarkers, guiding decisions on diagnosis, prognosis, and treatment selection. In cancer care, biomarker testing can reveal genetic mutations or protein expression patterns that indicate whether a patient is likely to benefit from targeted therapies, immunotherapies, or clinical trials. Research shows that biomarker-driven treatments improve survival rates, enhance quality of life, reduce unnecessary procedures, and lower overall health care costs. Importantly, biomarker testing is not limited to oncology; it is increasingly applied across other diseases to optimize care. However, access remains uneven, with disparities affecting marginalized and rural communities, underscoring the need for policies that expand coverage and ensure equitable availability of these life-saving tools.

Call to Action

Currently, eighteen states have expanded insurance coverage of biomarker testing. The State of _____ has the opportunity to join this growing movement, ensuring equitable access to lifesaving screenings and reducing disparities in prostate cancer outcomes. We respectfully urge lawmakers in _____ to support legislation eliminating cost-sharing for prostate cancer screening. By doing so, the state will improve survival rates, and advance health equity. The American Urological Association (AUA) is committed to ensuring that cost is never a barrier to lifesaving care. That's why we advocate for legislation eliminating copayments, deductibles, and coinsurance for prostate cancer screening, particularly for men at higher risk. Removing financial barriers helps reduce disparities and ensures more men receive timely, recommended screenings.

Social Media:

- Cost should never be a barrier to preventive care. Coverage for biomarker testing must align with mammograms and colonoscopies to ensure equitable access.
- Biomarker testing helps avoid unnecessary procedures by identifying which cancers need immediate care and which can be safely monitored. Smarter treatment, fewer risks. #PatientFirst
- Marginalized and rural communities are less likely to access biomarker testing. Expanding coverage reduces disparities and strengthens cancer care outcomes. #HealthJustice
- Biomarker testing reduces overtreatment and unnecessary biopsies, saving lives and lowering costs. Coverage expansion is a win for patients and the health care system. #ValueInCare

Sample Email

Subject: Support Needed: Biomarker Testing

Dear [Legislator's Name],

I urge your support for legislation that would ensure coverage of biomarker testing when medically appropriate for diagnosis, treatment, management, or monitoring. Biomarker testing is a critical gateway to precision medicine, enabling early detection, targeted therapies, and reduced costs, particularly in prostate cancer where combining urine tests with PSA can cut unnecessary biopsies by up to 41%. Expanding coverage will improve outcomes, lower costs, and reduce disparities, ensuring all patients have access to the right treatment at the right time.

Thank you for your leadership and commitment to public health.

Sincerely, [Your Name] [Your Contact Information]

Sample Letter

Date

Hon. First Last
Chair, Committee

Hon. First Last
Ranking Member, Committee

Re: ***Support _____ – Coverage for Biomarker Testing***

Dear Chairman and Ranking Member:

On behalf of the American Urological Association (AUA) we are writing to express our support for _____, which would ensure the coverage of biomarker testing for _____, when medically appropriate, for diagnosis, treatment, management, or ongoing monitoring. Progress in improving cancer outcomes increasingly involves the use of precision medicine, which uses information about a person's own genes or proteins to prevent, diagnose, or treat diseases like cancer. Biomarker testing is an important step in accessing precision medicine, which includes targeted therapies that can lead to improved survivorship, better quality of life, and reduced costs.

The AUA is a globally engaged organization with more than 22,000 physician, physician assistant, and advanced practice nursing members in more than 100 countries. Our members represent the world's largest collection of expertise and insight into treating urologic disease. Of the total AUA membership, more than 15,000 are based in the United States and provide invaluable support to the urologic community by fostering the highest standards of urologic care through education, research, and the formulation of health policy.

Biomarker testing is increasingly important for cancer care – and for treating other diseases. A 2021 report showed that 37 of the 62 oncology drugs launched in the past five years require or recommend biomarker testing before use.[1] Biomarker testing is increasingly important to enrolling patients in clinical trials as the number and percentage of cancer clinical trials that involve biomarkers has grown significantly. [2]

Precision treatments in cancers through biomarker testing have been shown to reduce costs and improve quality of life, which is particularly important to the AUA, State Society, and our members in the prostate cancer space. The use of a urine sample in conjunction with a prostate specific antigen (PSA) test has been shown to reduce the number of unnecessary biopsies of the prostate by up to 41%, compared to 11% with a PSA test alone.[3] With the American Cancer

Society projecting prostate cancer to have the highest rate of new cancer cases in the state in [3]2025, 950,[4] reducing the number of unnecessary biopsies could significantly reduce costs to the health care system as well as complications.

Not all communities benefit from the latest biomarker testing and precision medicine advancements. Communities that have been marginalized, including communities of color and individuals with lower socioeconomic status, are less likely to receive biomarker testing.[5] People in rural communities and those receiving care in nonacademic medical centers are also less likely to have access to biomarker testing.[6,7] Improving access to biomarker testing and, thereby, access to targeted therapies is also an important strategy to reduce health disparities and improve outcomes for cancer patients. Legislation to expand coverage of biomarker testing in Washington would allow more patients to get the right treatment at the right time. For these reasons, we respectfully request that the committee advances H 1227 and S 809 for consideration by the entire Legislature.

For more information or questions, we are happy to serve as a resource.

Sincerely,

1. IQVIA Institute (2021). *Global Oncology Trends 2021*. Retrieved January 2025.
2. Personalized Medicine Coalition. (n.d.). *The evolution of biomarker use in clinical trials for cancer treatment.* Retrieved from https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/The_Evolution_of_Biomarker_Use_in_Clinical_Trials_for_Cancer_Treatments.pdf
3. Tosoian, J. J., Zhang, Y., Xiao, L., et al. (2024). Development and validation of an 18-gene urine test for high-grade prostate cancer. JAMA Oncology, 10(6), 726–736. https://doi.org/10.1001/jamaoncol.2024.0455
4. American Cancer Society. (n.d.). *Cancer statistics center: Prostate cancer.* Retrieved January 17, 2025, from https://cancerstatisticscenter.cancer.org/#!/cancer-site/Prostate
5. Presley, C., Soulos, P., Chiang, A., Longtine, J., Adelson, K., Herbst, R., Nussbaum, N., Sorg, R., Abernethy, A., Agarwala, V., & Gross, C. (2017). Disparities in next generation sequencing in a population-based community cohort of patients with advanced non-small cell lung cancer. *Journal of Clinical Oncology, 35*(15_suppl), 6563–6563. https://doi.org/10.1200/JCO.2017.35.15_suppl.6563
6. Kim, E. S., Roy, U. B., Ersek, J. L., King, J., Smith, R. A., Martin, N., Martins, R., Moore, A., Silvestri, G. A., & Jett, J. (2019). Updates regarding biomarker testing for non-small cell lung cancer: Considerations from the National Lung

Model State Legislative Language:

IN THE GENERAL ASSEMBLY
"Biomarker Testing and Prostate Cancer Screening and Coverage Act"

Be it enacted by the People of the State of _____, represented in the General Assembly:

Section I. Title This Act shall be known and may be cited as the *Biomarker Testing and Prostate Cancer Screening Coverage Act*.

Section II. Purpose The purpose of this Act is to improve patient outcomes by requiring health benefit plans to provide coverage for biomarker testing when medically appropriate for diagnosis, treatment, care management, or ongoing monitoring. This Act seeks to expand access to precision medicine, reduce unnecessary procedures, lower health care costs, and promote equitable access to prostate cancer screening.

Section III. Definitions Coverage of biomarker testing.
(a) The following definitions apply in this section:

a. "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medication being considered for use or already being administered. This term includes gene mutations, characteristics of genes, and protein expression.
b. "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. This term includes single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.
c. "Consensus statement "means a statement developed by an independent multidisciplinary panel, aimed at specific clinical circumstances, and based upon
d. the best available evidence for the purpose of optimizing the outcomes of clinical care.
e. "FDA" means The United States Food and Drug Administration.
f. "Independent multidisciplinary panel" means a multidisciplinary panel of experts that utilizes a transparent methodology and reporting structure and that has a conflict of interest policy.
g. "Independent organization or medical professional society" means an organization or medical professional society that utilizes a transparent methodology and reporting structure and that has a conflict of interest policy.
h. "Nationally recognized clinical practice guidelines" means –evidence-based clinical practice guidelines developed by independent organizations or medical

professional societies that establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options, including recommendations intended to optimize patient care.

Section IV. Prostate Cancer Screening and Coverage of Biomarker Testing

(a) A health benefit plan shall provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate care management, or ongoing monitoring of an insured's disease or condition when the testing is supported by medical and scientific evidence.

(b) At a minimum, any of the following shall be considered support for biomarker testing:

1. Label indications for a test that has been FDA-approved or FDA-cleared.
2. Indicated tests for an FDA-approved drug.
3. Warnings and precautions on an FDA-approved drug label.
4. National coverage determinations developed by the Centers for Medicare and Medicaid Services.
5. Local coverage determinations developed by a Medicare Administrative Contractor.
6. Nationally recognized clinical practice guidelines and consensus statements.

(c) Coverage required under this section shall be provided in a manner that limits disruption in patient care, including the need for multiple biopsies or biospecimen samples.

(d) For prostate cancer screening specifically, coverage shall include biomarker testing used in conjunction with prostate-specific antigen (PSA) testing to reduce unnecessary biopsies and improve patient outcomes