

Biomarker Testing: Advancing Precision Medicine in Cancer Care

When used in the treatment of cancer, precision medicine uses information about a person's own genes or proteins to inform diagnosis, prognosis, therapy selection, and to monitor how well therapy is working.

The knowledge and practice of precision medicine in cancer have been progressing rapidly and advances have led to targeted cancer therapies, which work by interfering with specific cellular processes involved in the growth, spread, and progression of cancer.

Biomarker testing can help determine the best treatment for a patient.

Treatment with targeted therapy often requires diagnostic testing to analyze biological samples (e.g., blood, tumor tissue) taken from a patient to identify and evaluate specific biomarkers. Research shows that targeted therapy can improve patient survival and quality of life. When doctors connect patients to the most effective treatment for their cancer, patients can avoid treatments that will be ineffective or have more adverse side effects.

Biomarkers are an essential part of precision medicine, providing insight into physiological processes, medical conditions, or diseases. Cancer biomarkers can include molecules like proteins or genetic alterations such as mutations, rearrangements, or fusions.

Biomarker testing is the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests, multi-plex panel tests, and partial or whole genome sequencing. The results of these biomarker tests can help determine the best treatment plan for a specific patient, including precision medicines.



Testing patients for specific biomarkers is integral to precision medicine in cancer care. Despite evidence pointing to the clinical benefits associated with biomarker testing, routine clinical use does not always follow, and testing rates lag behind clinical guideline recommendations.

• In a 2021 survey, 66% of oncology providers reported that insurance coverage for biomarker testing is a significant or moderate barrier to appropriate biomarker testing.ⁱ

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 A 2022 analysis found that 71% of insurance policies are *more restrictive* than the National Comprehensive Cancer Network (NCCN) guidelines for biomarker testing of advanced breast, lung, melanoma, and prostate cancers.ⁱⁱ Nearly 9 in 10 providers rely on NCCN guidelines in determining when to recommend biomarker testing.ⁱⁱⁱ

Expand Access to Biomarker Testing and Precision Medicine:

Insurance coverage for biomarker testing is failing to keep pace with innovations and advancements in treatment. We must work to dismantle barriers that prevent *all* patients from benefiting from biomarker testing and precision medicine **ACS CAN supports expanding appropriate coverage of biomarker testing for public and private insurance plans. Without action to expand coverage and access to biomarker testing, advances in precision medicine could increase existing disparities in cancer outcomes by race, ethnicity, income, and geography.**



Legislative Action to Expand Coverage of Biomarker Testing

Legislation enacted: AR*, AZ, CA, GA, IL, KY, LA, MD, MN, NM, NY, OK, RI, TX Legislation introduced/expected in 2024: CO, CT, IA, IN, FL, MA, ME, NJ, NV, OH, PA, WA, WV *Commercial coverage only

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ⁱ ACS CAN. "Survey Findings Summary: Understanding Provider Utilization of Cancer Biomarker Testing Across Cancers." December 2021. https://www.fightcancer.org/sites/default/files/national_documents/provider_utilization_of_biomarker_testing_polling_memo_dec_2021.pdf

ⁱⁱ Wong WB, Anina D, Lin CW, and Adams D. Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors. Per Med 2022; 10.2217/pme-2021-0174.

ⁱⁱⁱ ACS CAN. "Survey Findings Summary: Understanding Provider Utilization of Cancer Biomarker Testing Across Cancers." December 2021. <u>https://www.fightcancer.org/sites/default/files/national_documents/provider_utilization_of_biomarker_testing_polling_memo_dec_2021.pdf</u>