

Recommendations to Improve Access to Biomarker Testing in Cancer



Barriers to biomarker testing can arise beginning at test development and persist through the interpretation of test results in the clinic. As precision medicine shifts the way health care providers and patients think about cancer treatments, it will be important to identify and address obstacles to appropriate biomarker testing. Addressing these barriers will require buy-in from diverse stakeholders across the health care system. ACS CAN proposes the following recommendations to increase the uptake of testing and advance the use of precision medicine in cancer care:

Patient Considerations

Insurer coverage is important for provider uptake and patient access to cancer biomarker testing. However, coverage of tests differs across the multiple public and private payers in the U.S. health care system.

1. Payers should provide coverage for FDA-cleared or -approved companion and complementary diagnostics as necessary to evaluate patient eligibility for a given targeted cancer therapy, and all National Comprehensive Cancer Network (NCCN) guideline-indicated biomarker tests.
 - a. Coverage of biomarker testing should not be arbitrarily constrained to specific cancer stages (e.g. III, IV, metastatic), but rather coverage should follow guideline recommendations and FDA-cleared or -approved uses.
 - b. Payers should ensure that any utilization review practices (e.g. prior authorization) are timely and efficient and do not delay the initiation of biomarker testing after a diagnosis.
 - c. Coverage of biomarker testing should not be restricted to one single occurrence and should allow for retesting after a medically appropriate interval, indication of a change in the genetic makeup of the patient's cancer (e.g. such as acquired resistance), or if the test is designed to monitor disease progression and therefore must be serially administered.
 - d. Payers should provide coverage for multi-gene panel testing as indicated by NCCN guidelines, when it is more efficient, when a single analyte test does not exist, or when tissue availability is too limited for use of multiple single analyte testing.
 - e. Coverage should be provided for tumor-agnostic biomarker tests as medically appropriate.
2. Payers should provide coverage and access to genetic counseling prior to and after the interpretation of biomarker tests.
3. Comprehensive biomarker testing provides value beyond therapy selection, and results from testing should be utilized to inform patients of relevant clinical trial opportunities.

Provider and Institutional Considerations

Providers and institutions have a significant impact on which patients receive cancer biomarker testing and consequently whether they receive targeted cancer therapy. Despite evidence pointing to the clinical benefits, testing rates lag behind clinical guidelines and advancements in the field.

1. Biomarker tests should be reliable, valid, and relevant to a patient's cancer diagnosis. This should be realized with a harmonized system of regulatory oversight for all biomarker tests that features tiered requirements based on the risk posed by a given biomarker test.
2. Providers and institutions should be equipped with tools (e.g. clinical decision support), resources (e.g. access to a tumor board), and training for the efficient and sufficient collection and handling of tissue for testing, and for proper test selection, administration, and interpretation.
 - a. Quality measures and accreditation standards should promote adoption and utilization of clinical decision support tools for biomarker testing that incorporate evidence-based clinical guidelines at the point of care to guide testing and treatment decisions.
 - b. High-quality clinical biomarker testing guidelines should adhere to guideline development best practices including appropriate transparency, conflict of interest rules, systematic evidence review, and timely updating.
 - c. Licensing and clinical specialty boards should encourage use of current biomarker testing guidelines through continuing education requirements.