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Position Statement on Biomarker Testing

Position: BIO supports timely, appropriate, and equitable access to biomarker testing as well as adequate coverage and reimbursement by public and private payers when testing is supported by clinical guidelines or peer-reviewed scientific evidence. Delays in biomarker testing and coverage may lead to worse outcomes for patients.
Continuing advances in science and genomics are driving an increased understanding of human physiology and how diseases affect the body; these advances are helping researchers identify new biomarkers. As more biomarkers are identified, they have the potential to greatly enhance the drug development process by providing researchers with new ways to measure disease activity, reduce the amount of time required to show a medicine is safe or effective, and enable the development of more personalized, precision medicine— particularly where multiple biomarkers can inform the use of targeted drug combinations. Biomarkers can also allow researchers to better understand how effective a treatment is against a disease with endpoints that are difficult to define, providing clinicians with additional informative measurements in the early diagnosis of a disease and identifying differences in responses between individuals or subpopulations.

The development of personalized medicines that are more tailored to the individual patient using biomarkers helps drive efficiencies and improvements in patient care. That is because biomarkers can help identify those most likely to benefit from a specific treatment. For example, biomarkers are often used in cancer treatments to identify patients with tumors expressing certain genomic characteristics that indicate those patients are likely to respond to a targeted cancer therapy. In another example, they can be used to ensure that a certain patient with a rare disease will most likely benefit from a specific therapy, such as a gene therapy.

Access to biomarker testing should not be delayed, as this may have detrimental effects on patient outcomes. If patients do not have access to biomarker testing, they may not be offered life-saving targeted therapies that can improve their overall health outcome. Additionally, it is important that if access to a particular therapy is dependent upon a specific biomarker, coverage policies must reflect the new advances in treatment. Coverage policies should never stand in the way of access to treatment.

Biomarker testing for the purposes of diagnosis, treatment and ongoing patient monitoring is not done through at home genetic DNA testing. It is done in clinical laboratory by healthcare professionals working within the scope of their license and experience to identify the presence of one or more biomarkers in a patient's sample. A patient's health care provider must always have the ability to order all comprehensive biomarker testing panels necessary to ensure appropriate treatment and continuing care.

Disparities in access to biomarker testing exist across the United States. Coverage expansion and accessibility to biomarker testing can mitigate disparities in health outcomes by race, ethnicity, income, and geography. A recent research report concluded there are geographic variations in the number of commercial lives within each state under a more restrictive multigene panel test (MGPT) coverage policy.[1] More specifically, the report found that a total of 34 states had 50% or more fully insured commercial lives covered by a plan classified as more restrictive than the clinical guidelines.[2]

BIO supports the continual assessment of coverage requirements by public and private payers to ensure coverage keeps pace with scientific innovation and advances in clinical care. Public, and private payers should regularly review clinical guidelines, existing medical compendia, CMS coverage guidelines, recommendations of health professional organizations, and consensus statements to update their testing policies.

Biomarker testing should not be subject to lifetime limits. As disease stages progress over time and can vary from patient to patient, biomarker testing should be covered for all relevant panels of tests at any time in the continuum of care, if determined necessary by a health care professional.

[1] *Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors* - William B Wong, Daniele Anina, Chia-Wei Lin, and Devon V Adams
Personalized Medicine 2022 19:3, 171-180
[2] Ibid.

Definitions:

(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 medications being considered for use or already being administered. Biomarkers include but are not limited to gene mutations, characteristics of genes, or protein expression.

(b) “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, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

(c) “Consensus statements” as used here are statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict-of-interest policy. These statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(d) “Nationally recognized clinical practice guidelines” as used here are evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict-of-interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.