

Talking points on biomarker testing

Importance of biomarker testing:

- Progress in improving cancer outcomes increasingly involves the use of *precision medicine*.
- Biomarker testing is important step for accessing precision medicine including targeted therapies that can lead to **improved survivorship and better quality of life for cancer patients**.
 - Nearly 60% of all cancer drugs approved in the last 5 years require or recommend biomarker testing before use.ⁱ
 - Biomarkers may guide doctors' treatment decisions by providing information about whether patients will respond to particular treatment options.ⁱⁱ
 - Cancer clinical trials are increasingly driven by biomarkers and the development of targeted therapies - From 15% in 2000 to 55% in 2018ⁱⁱⁱ
- Biomarker testing is increasingly important for cancer care – and for the treatment of other diseases including arthritis, other autoimmune conditions and rare diseases, with research happening in many other areas including Alzheimer's, other neurological conditions, cardiology and more.

What is biomarker testing?

- **In cancer care, biomarkers are often used to help determine the best treatment for a patient.**
 - A *biomarker* is a sign of a normal biological process, disease or abnormal function that can be measured; these markers are often gene mutations or protein expressions.
- *Biomarker testing* is the analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker.
 - Diagnostic biomarkers are used to confirm presence of a disease or condition, or to identify individuals with a subtype of the disease. This is one of the earliest uses of biomarker testing in cancer.
 - Prognostic biomarkers are used to identify the likelihood of disease recurrence or progression in patients after diagnosis.
 - Pharmacogenomic (PGx) biomarkers are used to predict a drug's efficacy or likelihood of toxicity. The same treatment given to patients with the same disease can produce different responses based on each person's *inherited genes*.
 - Predictive biomarkers are used to help doctors to identify the most effective treatment for a patient. These biomarkers help to identify individuals who are more likely than those without the biomarker to experience a favorable (or unfavorable) response to a treatment or therapy.
 - Monitoring biomarkers can show signs of disease progression or recurrence earlier than traditional monitoring (like scans) and can monitor drug response or toxicity.
- *Single marker vs panel tests*
 - Often the most appropriate test for a patient will be a panel test that looks for several biomarkers rather than testing separately for individual biomarkers.
 - There is strong evidence that panel tests – while more expensive than single gene tests – lead to overall cost savings for testing and treatment for some patients.

BMT and Health Equity:

- **Not all communities are benefiting from the latest advancements in biomarker testing and precision medicine.**

- Communities that have been excluded including communities of color, individuals with lower socioeconomic status, rural residents, and patients receiving care in non-academic medical centers are less likely to receive biomarker testing.
- Improving coverage for and access to biomarker testing across insurance types is key to reducing health disparities.
- **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.**
- Both the National Black Caucus of State Legislators (NBCSL) and National Hispanic Caucus of State Legislators (NHCSL) adopted resolutions recognizing the importance of biomarker testing in advancing health equity and reducing disparities.

BMT and cost savings:

- **Timely access to appropriate biomarker testing can help achieve better health outcomes, improve quality of life and reduce costs** by connecting patients to the most effective treatment for their cancer.
 - **Comprehensive biomarker testing can allow patients to avoid treatments that are likely to be ineffective.**
 - **Biomarker testing can also identify patients at low risk for disease progression or recurrence, allowing them to avoid treatments that may not be beneficial or necessary.**

ACS CAN's position: Action is needed to address insurance coverage

- **Insurance coverage for biomarker testing is failing to keep pace with innovations and advancements in treatment.**
 - In a December 2021 survey, 66% of oncology providers reported that insurance coverage is a significant or moderate barrier to appropriate biomarker testing for their patients.
 - A 2022 peer-reviewed analysis in Precision Medicine found that 71% of policies are more restrictive than NCCN guidelines for biomarker testing in advanced breast, lung, melanoma and prostate cancers.
- We must remove barriers to biomarker testing and precision medicine, and ensure all patients—, regardless of race, ethnicity, gender, age, sexual orientation, socioeconomic status or zip code—benefit from better care.
- **ACS CAN supports policies that will expand appropriate coverage of biomarker testing for public and private insurance plans.**

ⁱ Global Oncology Trends 2021. IQVIA Institute; June 2021.

ⁱⁱ Devarakonda S, Govindan R. Biomarker-Driven Staging—Are We There Yet? JAMA Network Open. 2019;2(12):e1917052-e1917052.

ⁱⁱⁱ The Evolution of Biomarker Use in Clinical Trials for Cancer Treatment Key Findings and Implications. Personalized Medicine Coalition 2019.