

Biomarker Testing – Q&A

1. “Biomarkers” or “biomarker testing”?

- A “biomarker” is a sign of disease or abnormal function that can be measured in blood, tissue or other biospecimen.
- Biomarker testing is the analysis of a patient’s tissue, blood or other biospecimen for the presence of a biomarker. Biomarker testing includes single-analyte tests, multi-plex panel tests, and partial or whole genome sequencing.
- The results of biomarker tests can help health care providers match a patient to precision medicine. Biomarker testing allows doctors to deliver the right treatment to the right patient at the right time.
- This legislation is an effort to expand access to comprehensive biomarker testing, which includes single-analyte tests, multi-plex panel tests, and partial or whole genome sequencing.

2. Is this genetic testing?

- No, biomarker testing analyzes tumor samples to identify somatic (acquired) or germline (inherited) mutations that impact treatment decisions. Biomarker testing is used in people who have **already been diagnosed with cancer**. This is separate from genetic testing for inherited risk which looks for inherited mutations to identify individuals who may be a higher risk for later developing cancer or current cancer patients whose family members may want to get genetic testing and counseling.
- However, some inherited genetic mutations (e.g. BRCA for breast cancer) can help inform treatment decisions and testing for those markers would be covered by our legislation. *BRCA testing can be done at or after a cancer diagnosis to inform prognosis and treatment options (this would be biomarker testing) or it can be done before a patient has been diagnosed with cancer, based on family history, to assess risk for developing cancer (what we describe as genetic testing).*

3. Genetic testing to determine risk for later developing cancer would not be covered under “diagnosis, treatment, appropriate management, or ongoing monitoring.” Are other words used to describe biomarker testing?

- Mutation testing, genomic testing, molecular testing and molecular profiling, tumor profiling are all other terms for biomarker testing. ACS CAN uses biomarker testing.
- Biomarker testing is sometimes subdivided into diagnostic biomarkers, prognostic biomarkers and predictive biomarkers. Our legislation covers all these types of biomarker testing when supported by clinical treatment guidelines.
- The results of biomarker testing are key to precision oncology – which can include: targeted therapy, hormone therapy, immunotherapy and stem cell or cell-based therapy.

4. Why limit to small employer/individual insurance plans?

- Large employer plans are regulated at the federal level and not subject to state regulations. This is true for all insurance issues we work on. Generally speaking, large employer sponsored plans tend to have better coverage of biomarker testing.

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5. Cost implications – isn't this going to be expensive?

- Biomarker testing is not indicated or appropriate for all cancer patients. We are not advocating for universal biomarker testing; rather, this legislation is tied to rigorous sources of medical and scientific evidence that guide who should receive this testing (FDA, CMS coverage determinations, nationally recognized clinical practice guidelines – e.g., NCCN and ASCO).
- Use of guideline-indicated biomarker testing can help avoid the costs of treatments that will be ineffective and avoid unnecessary disease progression. **Connecting patients with the most effective treatments can improve survival and quality of life.**

6. This legislation gets ahead of science/ requires plans to cover unproven tests/ should be limited to clear applications (e.g., lung and breast cancer only or FDA-approved tests only).

- The legislation is tied to respected and rigorous sources of medical and scientific evidence (FDA, CMS coverage determinations, nationally recognized clinical practice guidelines). Including nationally recognized clinical practice guidelines will ensure coverage keeps pace with innovation and advances in health care.