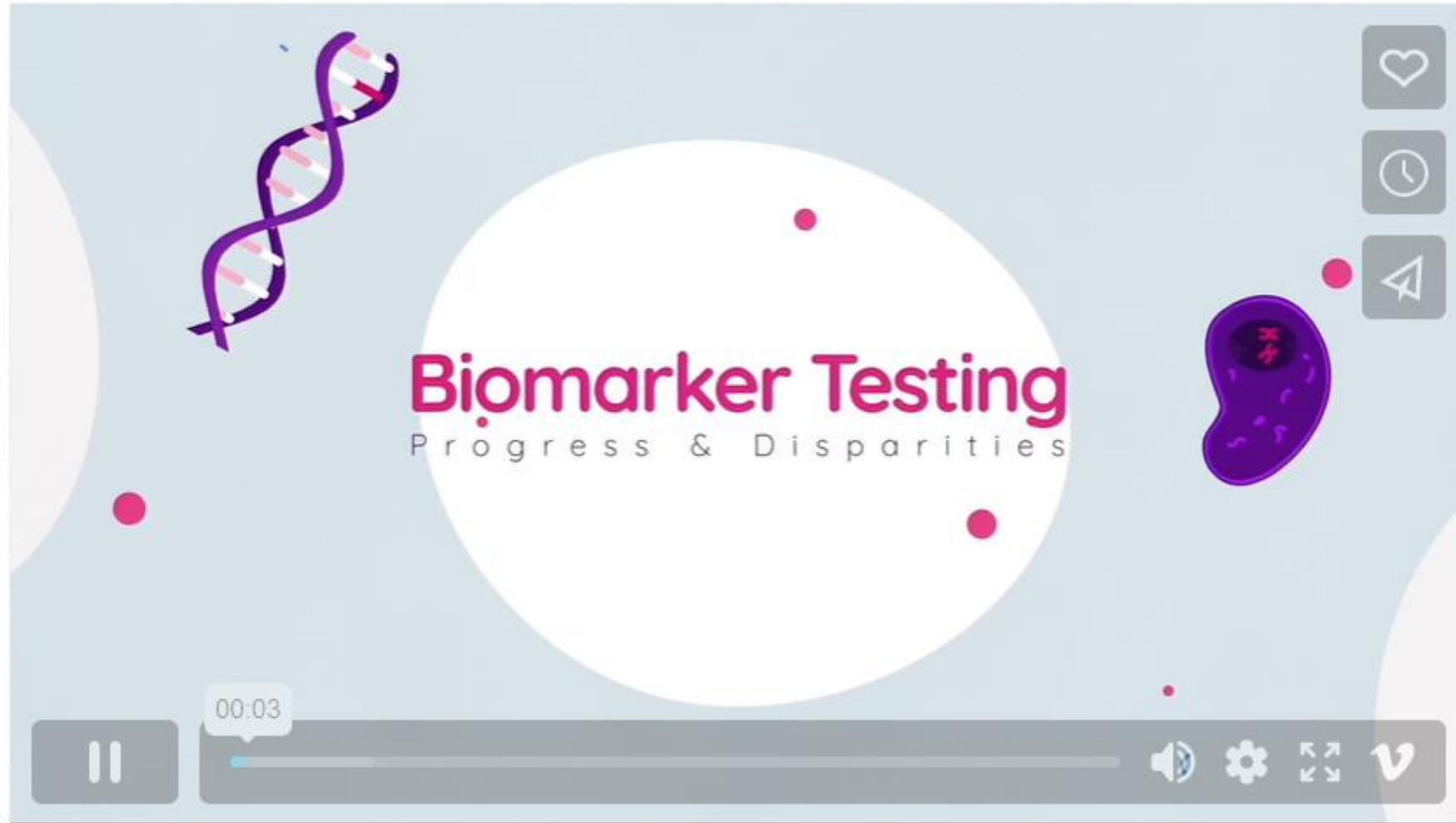


Biomarker Testing and Precision Medicine

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Biomarkers and Precision Medicine



Biomarkers and Precision Medicine

Biomarkers - 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. Includes *gene mutations* or *protein expression*.

The right treatment, for the right patient, at the right time

- An essential component of precision medicine
- Targeted cancer therapy
- Avoidance of therapies unlikely to provide clinical benefit

Not just about cancer:

- Being explored in a variety of disease areas (e.g., cardiology, rheumatology, neurology, infectious, respiratory, autoimmune diseases)



Screening vs. Genetic testing vs. Biomarker testing

Screening tests – like MCEd, mammograms, PSA testing

Looking for signs of cancer in general population

Genetic testing

Testing for inherited risk to determine risk for developing certain cancers or passing risk onto children

Biomarker testing

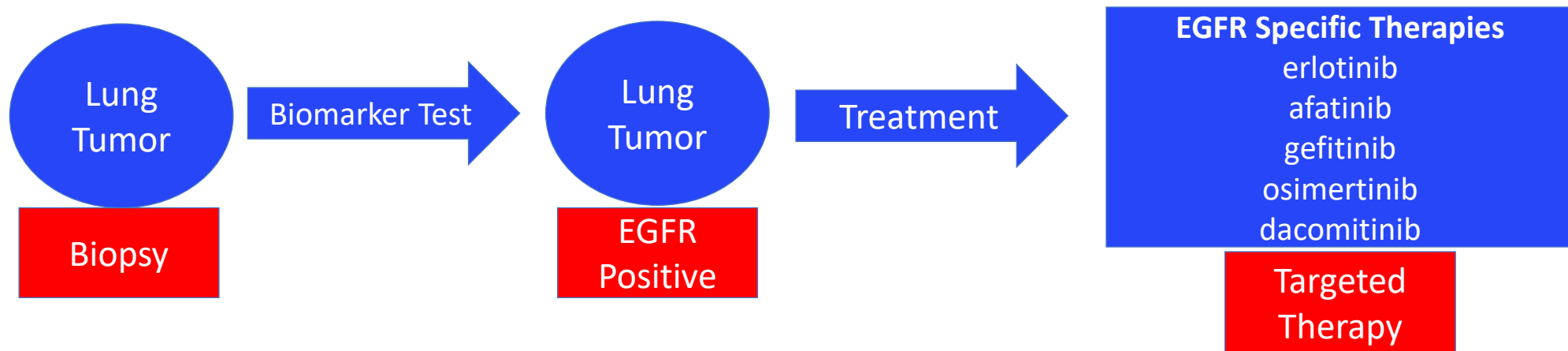
Used in people who already have cancer to determine best treatment options, how aggressive the disease is, monitor for recurrence



What is biomarker testing?

Biomarker testing in people with cancer

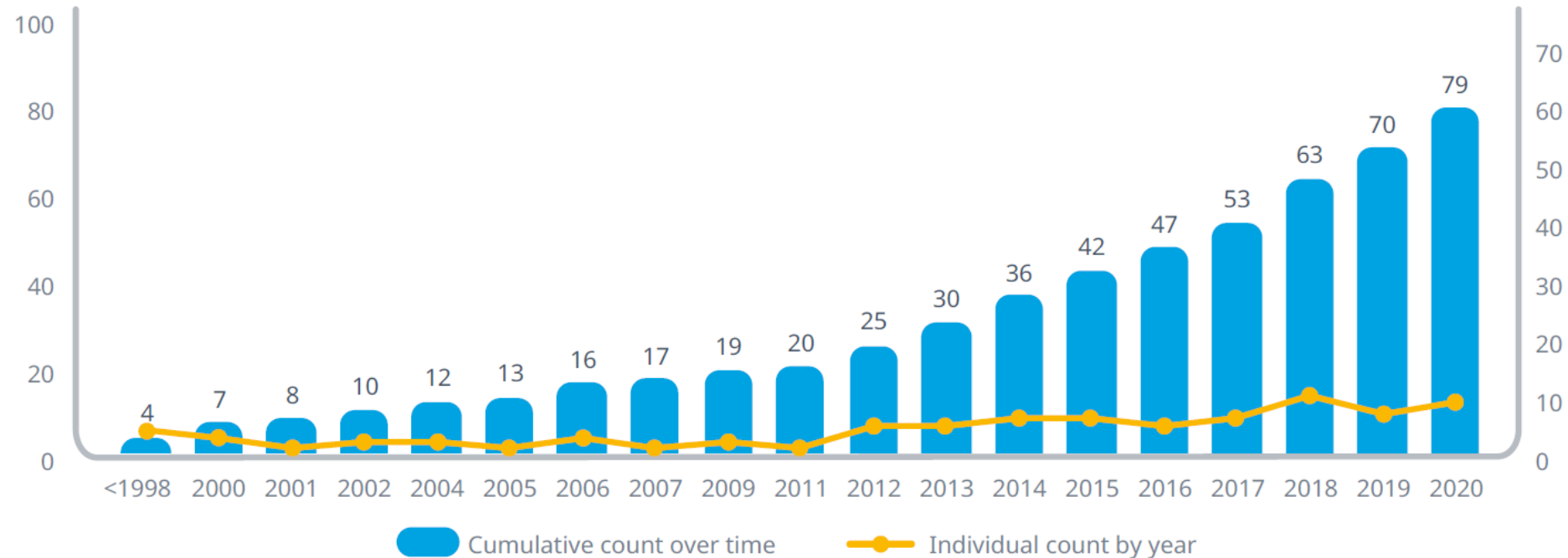
- Looks for the presence of molecules like proteins or gene mutations found in cancer cells
- Can be used to inform therapy selection and treatment decisions
- Example: EGFR-positive non-small cell lung cancer --> several EGFR inhibitors



Trends in biomarker testing

Nearly 80 oncology medicines are used after a predictive biomarker test up from 20 in 2011

Exhibit 38: Number of U.S. Oncology Medicines with Required or Recommended Predictive Biomarker Testing



Source: IQVIA Institute, May 2021



Biomarker testing and clinical trials

Cancer clinical trials are increasingly driven by biomarkers and the development of targeted therapies

- From 15% in 2000 to 55% in 2018¹

Increasing access to biomarker testing key to supporting access to clinical trials

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



Who Should Get Tested and Why?

The Role of Clinical Guidelines in Determining Appropriate Testing

- Several professional associations have cancer biomarker testing and treatment guidelines
 - National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology, American Society of Clinical Oncology (ASCO), others
- Helps assure that testing and treatment take advantage of the latest knowledge
- Biomarker testing has become the standard of care in certain cancers

Patients who receive biomarker testing and are eligible for and receive targeted cancer therapy have better outcomes.



Who is Getting Tested?

Unequal access to testing

- In metastatic non-small cell lung cancer (NSCLC), **eligible Black patients are less likely to receive biomarker testing** compared to white patients.
- Patients with advanced NSCLC or colorectal cancer who were **Black, older, or Medicaid-insured** had **lower odds of next-generation sequencing biomarker testing** compared to patients who were white, younger, or commercially insured.
- There are **socioeconomic inequalities** in biomarker testing and targeted therapy utilization across cancer types.
- There **are lower rates of testing in community oncology settings versus academic medical centers**.

These disparities in access and use of guideline-indicated biomarker testing and targeted therapy can potentially widen existing disparities in cancer survival.



What does this look like for a patient?



Barriers: Insurance

Coverage of tests differs greatly across payers

- Coverage policies generally more common for single-gene tests vs. multi-gene panel tests

Plans aren't necessarily following the evidence

- A recent paper in *Personalized Medicine* highlights gaps between insurance coverage and clinical practice guidelines.
- Although 91% of plans evaluated reference NCCN treatment guidelines in their biomarker testing policies, **71% are “more restrictive” than these guidelines for biomarker testing in breast, non-small cell lung cancer, melanoma and/or prostate cancer patients.**

Wong, W., et al. (2022) *Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors.*



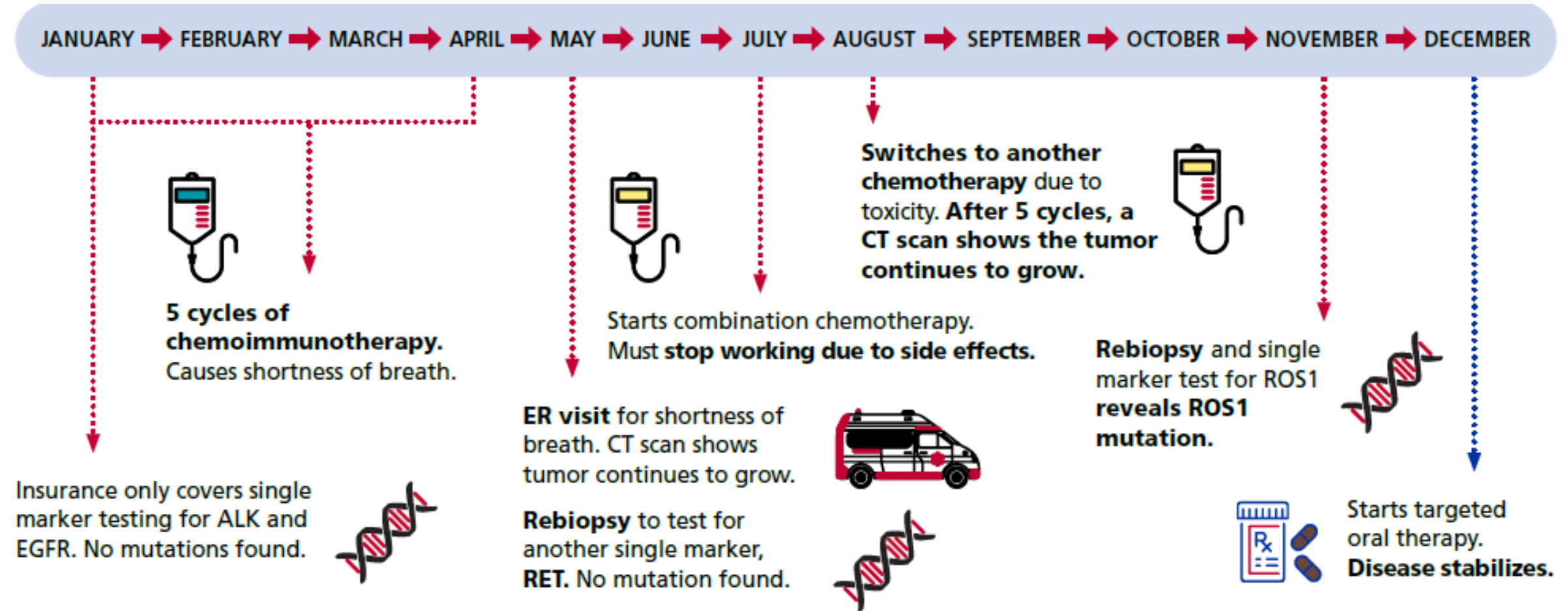
What does this look like for a patient?

Kathy is a 54-year-old white woman with no history of tobacco use. After visiting her primary care physician for persistent cough and shortness of breath, she was ultimately referred to an oncologist. Her oncologist ordered a diagnostic CT scan which revealed a large mass in the left lung with lymph node involvement. A biopsy confirmed stage IV non-small cell lung cancer, and her PET/CT scan was consistent with extensive bone metastases.



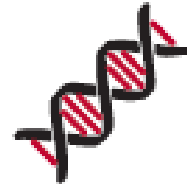
Kathy, 54
Lung Cancer Patient

Without Comprehensive Biomarker Testing



With Comprehensive Biomarker Testing

Comprehensive biomarker testing reveals a **ROS1** mutation.
Starts targeted oral therapy. **Disease stabilizes.**



JANUARY → FEBRUARY → MARCH → APRIL → MAY → JUNE → JULY → AUGUST → SEPTEMBER → OCTOBER → NOVEMBER → DECEMBER



Legislation to Address Coverage Gaps

Requires state-regulated insurance plans including Medicaid to cover comprehensive biomarker testing when supported by medical and scientific evidence

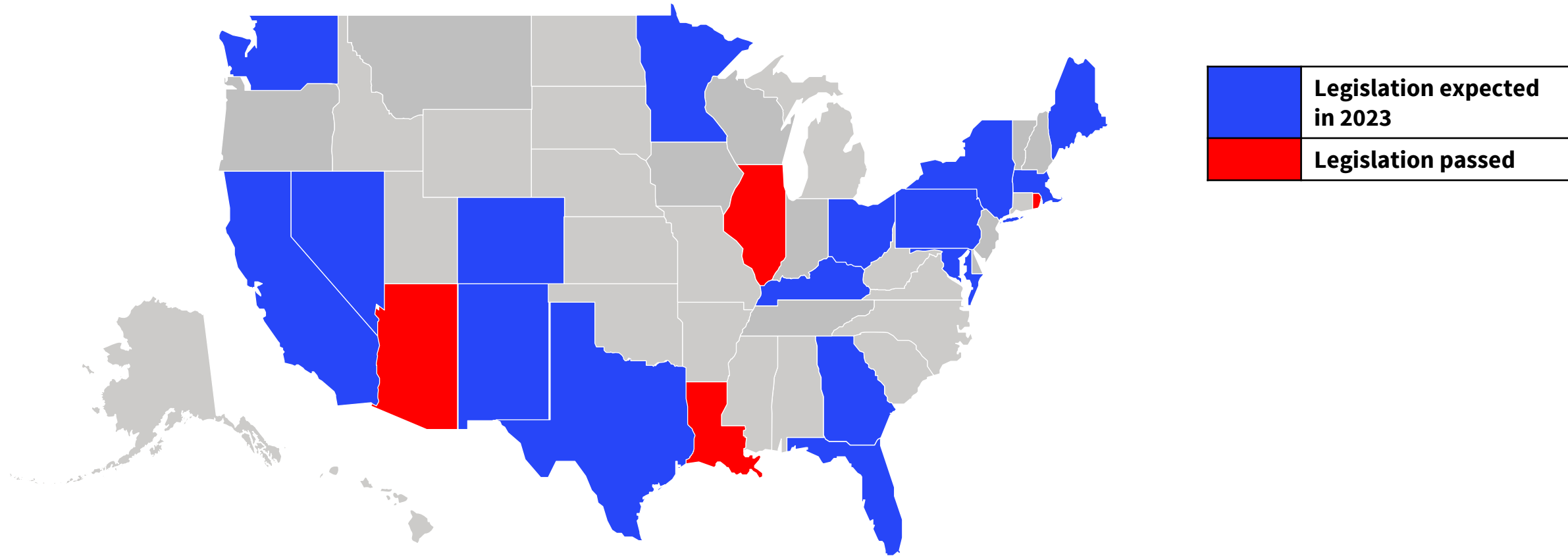
Biomarker testing must be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

1. Labeled indications for an FDA-approved or -cleared test
2. Indicated tests for an FDA-approved drug;
3. Warnings and precautions on FDA-approved drug labels
4. Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations and Medicare Administrative Contractor (MAC) Local Coverage Determinations; or
5. Nationally recognized clinical practice guidelines and consensus statements.

Disease and stage agnostic



Legislation to Expand Access to Biomarker Testing



Legislation passed: AZ, IL, LA, RI

Legislation expected in 2023: CA*, CO, FL, GA, KY, MA, ME, MD, MN, NV, NM, NY, OH, PA, TX, WA



Key Takeaways

- **Personalized treatments are helping cancer patients live longer and better.**
- **Biomarker testing helps connect patients with the most effective treatment for their cancer, and avoid treatments that will be ineffective.**
- **Without action to improve access to biomarker testing, some patients are left behind from the latest advances in cancer treatment.**



Learn more:

fightcancer.org/biomarkers

Questions?