

Biomarker Testing and Precision Medicine

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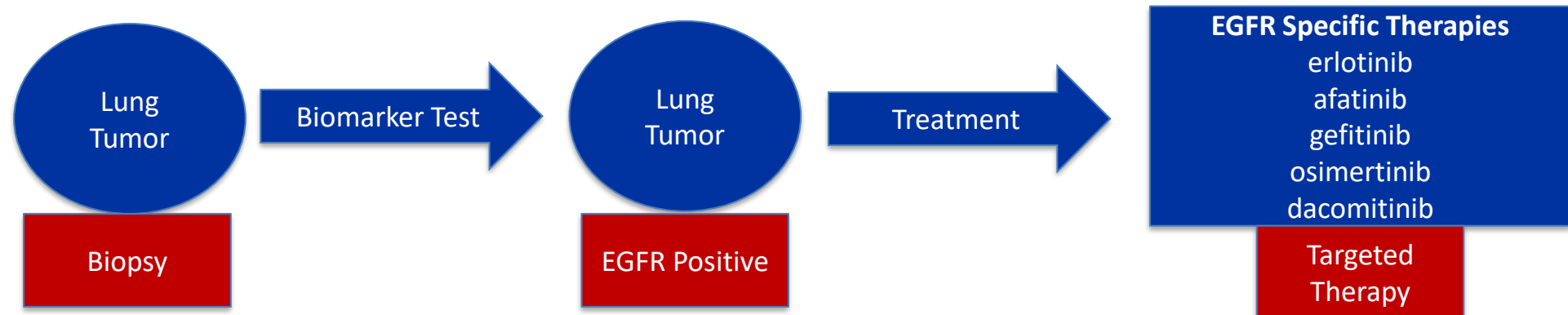
Biomarkers and Precision Medicine

- 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
- Biomarkers include but are not limited to gene mutations or protein expression
- An essential component of precision medicine connecting the **right patient** to the **right treatment** at the **right time**
 - Targeted cancer therapy
 - Avoidance of therapies unlikely to provide clinical benefit
- Being explored in a variety of disease areas (e.g., cardiology, rheumatology, neurology, infectious, respiratory, autoimmune diseases)



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



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
 - One way to 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.**



Single Marker Testing vs Panel Testing

- Some patients only need *single marker testing*.
- For other patients, *panels* testing for several or many different markers are most appropriate.
- Panel tests can make more efficient use of a tissue sample compared to multiple single-gene tests.

Barriers to Biomarker Testing

- Coverage of tests differs greatly across payers
- Coverage policies generally more common for single-gene tests vs. multi-gene panel tests
 - Commercial plan coverage policies for multi-gene panel tests are frequently more restrictive than what is recommended in NCCN clinical guidelines¹
- Patients who are older, Black, uninsured, or Medicaid-insured, or live in rural areas are less likely to be tested for certain guideline-indicated biomarkers^{2,3,4}
- Differential access can potentially widen existing disparities in cancer outcomes.



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

[2] Presley, C., et al. (2017). *Disparities in next generation sequencing in a population-based community cohort of patients with advanced non-small cell lung cancer.*

[3] Lamba, N., et al. (2020). *Disparities in microsatellite instability/mismatch repair biomarker testing for patients with advanced colorectal cancer.*

[4] Lewis, M.A., et al. (2021). *Biomarker testing in patients (pts) with metastatic colorectal cancer (mCRC): Survey of U.S. oncologists (ONC) in rural areas and urban clusters.*

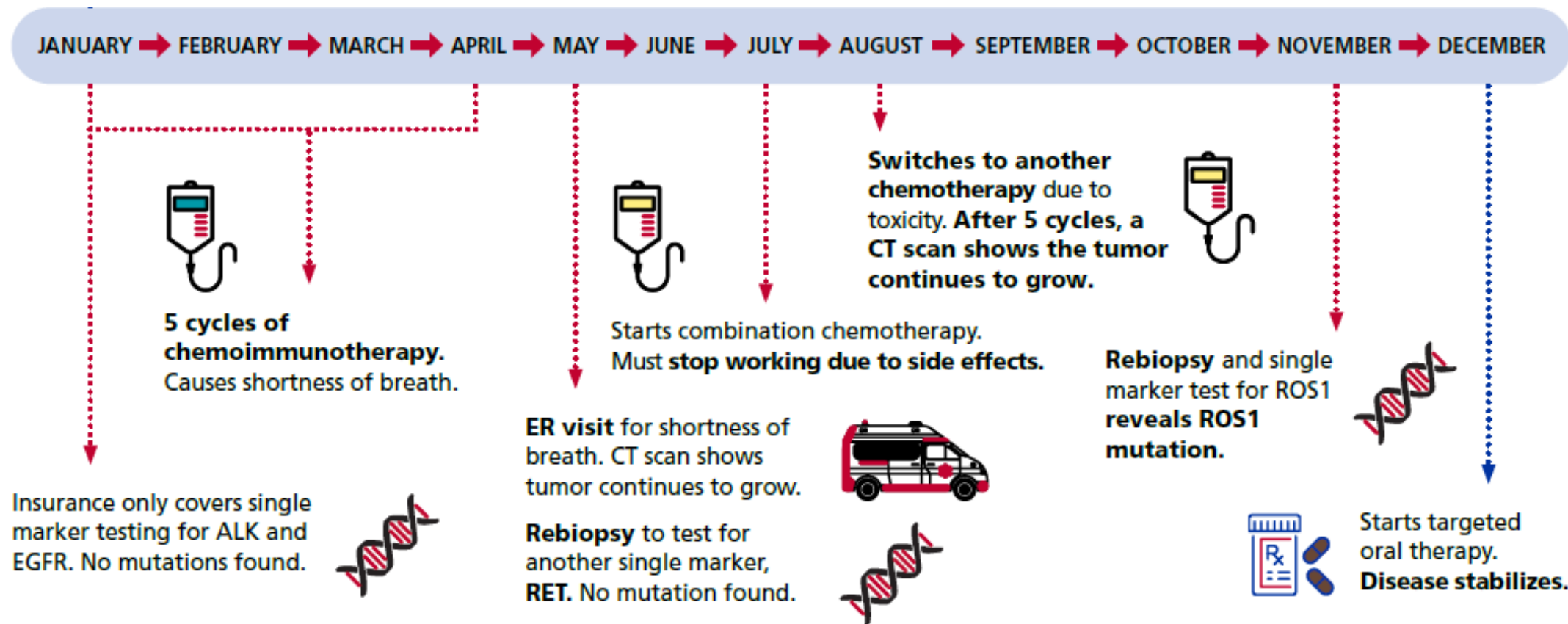
What does this look like for a patient?

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.



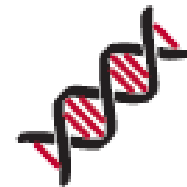
Kathy, 54
Lung Cancer Patient

Without Comprehensive Biomarker Testing



With Comprehensive Biomarker Testing

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



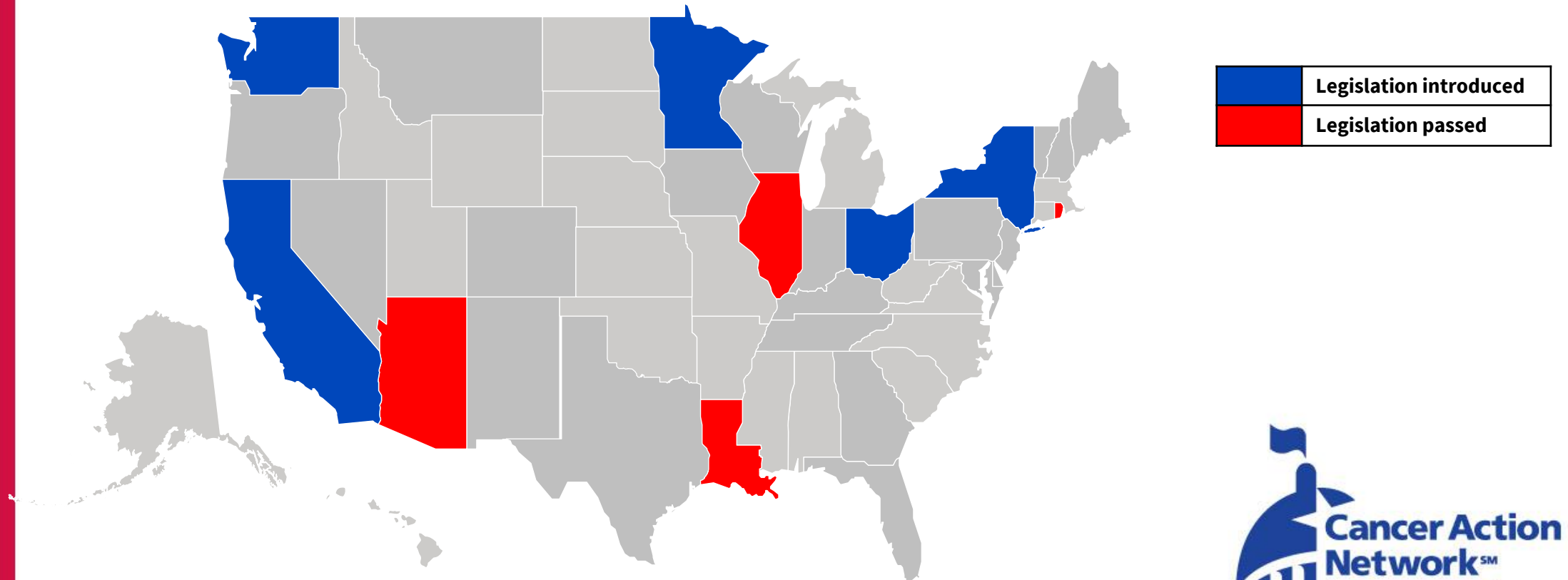
JANUARY → FEBRUARY → MARCH → APRIL → MAY → JUNE → JULY → AUGUST → SEPTEMBER → OCTOBER → NOVEMBER → DECEMBER



Better Outcomes. Lower Costs.

- Broad panel testing has been shown to optimize treatments in patients with lung cancer. Identifying the broader genomic landscape of a patient's tumor earlier empowers oncology providers and lung cancer patients with information to make timely, precise treatment decisions that are ultimately more cost effective.
- A 2020 study sponsored by CVS Health demonstrated that lung cancer patients who received broad panel sequencing had significantly lower overall treatment costs than patients who had smaller panel testing.
 - Narrow panel testing:
 - Average sequencing cost - \$719
 - Overall PMPM treatment cost - \$20,039
 - Broad panel testing:
 - Average sequencing cost - \$1,977
 - Overall PMPM treatment cost - \$11,535

Legislation to Expand Access to Biomarker Testing



Legislation introduced: CA, MN, NY, OH, WA
Legislation passed: AZ, IL, LA, RI



fightcancer.org/biomarkers

