NATIONAL LUNG CANCER ROUNDTABLE

American Cancer Society®

Project ECHO®

Addressing Lung Cancer Biomarker Testing Through Project ECHO: 2022-2023 Expansion

Session Five: Biomarker Testing and Precision Medicine

Welcome to Session Five:
ACS/NLCRT Lung Cancer Biomarker Testing Project ECHO

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Today's materials will be made available on echo.cancer.org

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Today's Agenda

01	**Agenda Preview & Introductions** (10 min)
02	**Didactic Presentation: Biomarker Testing and Precision Medicine** (15 min)
03	**Didactic Q/A** (5 min)
04	**Case Presentation** (5 min)
05	**Case Presentation Recommendations/Discussion** (10 min)
06	**Post-Session Poll & Wrap Up** (5 min)

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Additional thanks to Foundation Medicine

Central Time Combined Hub ACS Staff Team

Korey Hofmann, MPH
American Cancer Society
ECHO Coordinator

Hannah Burson
American Cancer Society
ECHO Tech Coordinator

Allison Rosen, MS
American Cancer Society
ECHO Tech Coordinator

Krista Kirksey Thomas
American Cancer Society
Arkansas
ECHO Coordinator

Jocelyn Phillips
American Cancer Society
Tennessee
ECHO Coordinator

Hannah Hogan
American Cancer Society
Texas
ECHO Coordinator

Sheena Robertson
American Cancer Society
Texas
ECHO Coordinator

Leigh Davis
American Cancer Society
Louisiana
ECHO Coordinator

Jasmyne Watts
American Cancer Society
Louisiana
ECHO Coordinator

Amy Williams
American Cancer Society
Louisiana
ECHO Coordinator

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Texas Spoke Sites

- University Medical Center El Paso
- Hospitals of Providence
- CHRISTUS Trinity Mother Frances Health System

TEXAS SESSION 5

Didactic Presentation: American Cancer Society Cancer Action Network

Cori Chandler, MPA

Sr. State & Local Campaigns Manager

American Cancer Society Cancer Action Network

Biomarker Testing and Precision Medicine

Cori Chandler, MPA
Senior Manager, State & Local Campaigns – Access to Care
American Cancer Society Cancer Action Network

Biomarkers and Precision Medicine

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

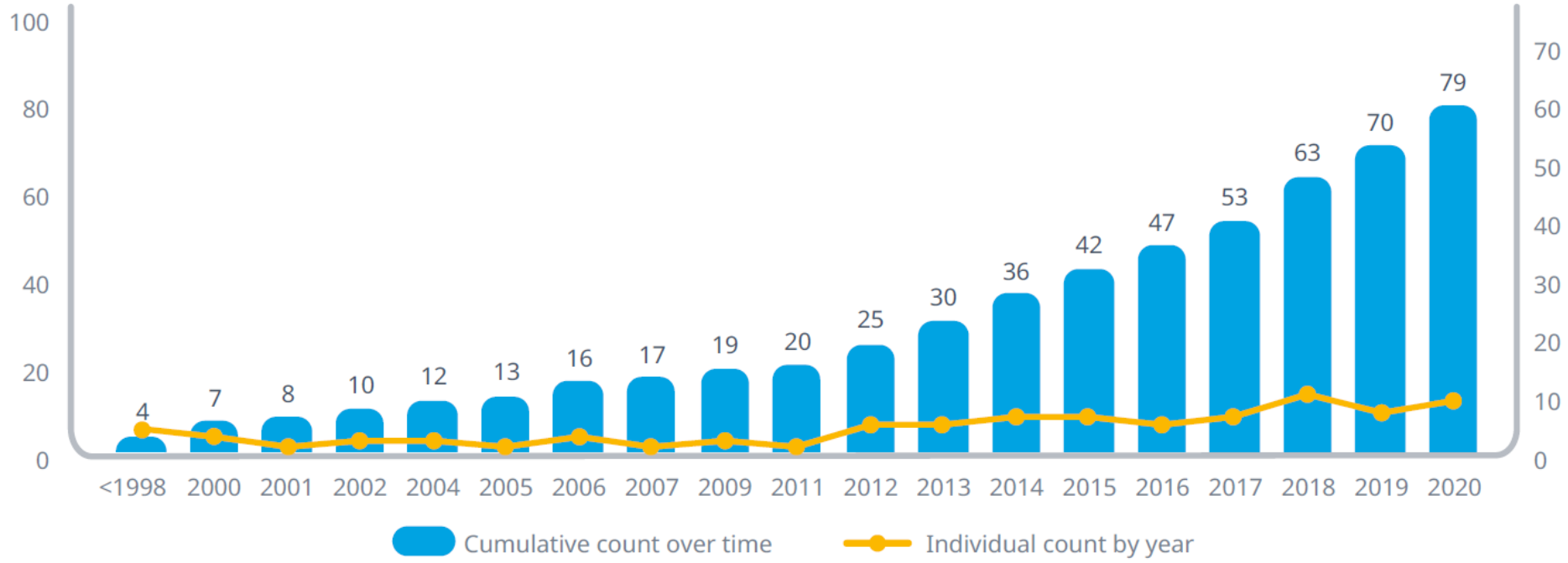
Biomarker testing

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

Trends in biomarker testing

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

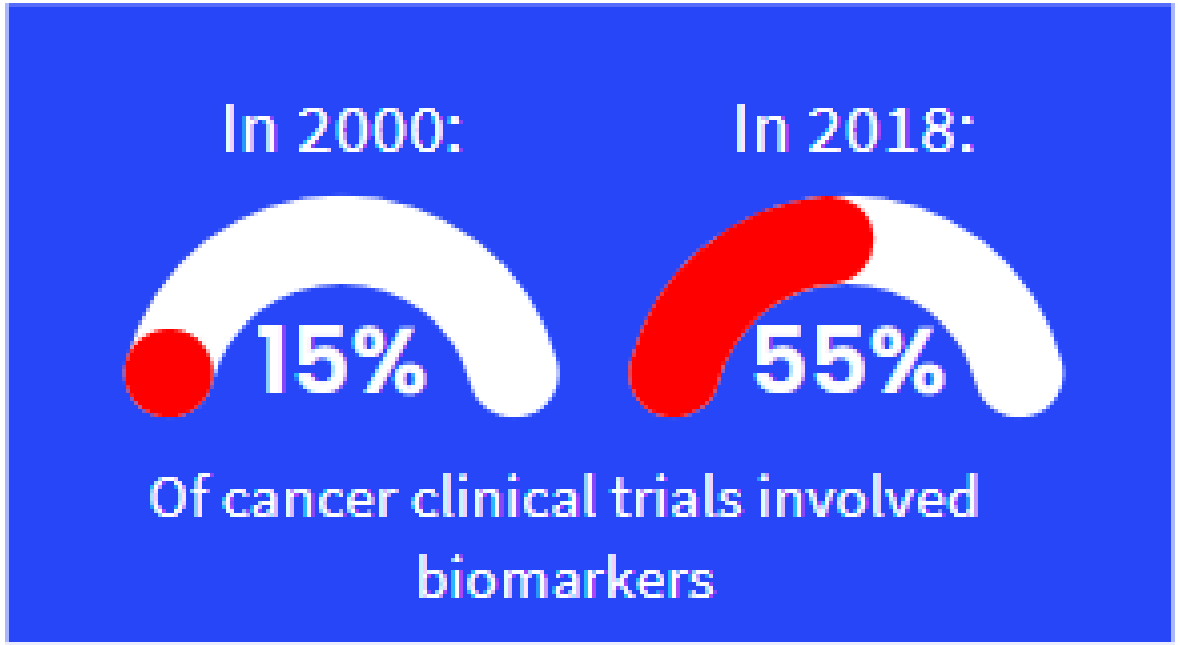
Exhibit 38: Number of U.S. Oncology Medicines with Required or Recommended Predictive Biomarker Testing



Source: IQVIA Institute, May 2021

Biomarker testing and clinical trials

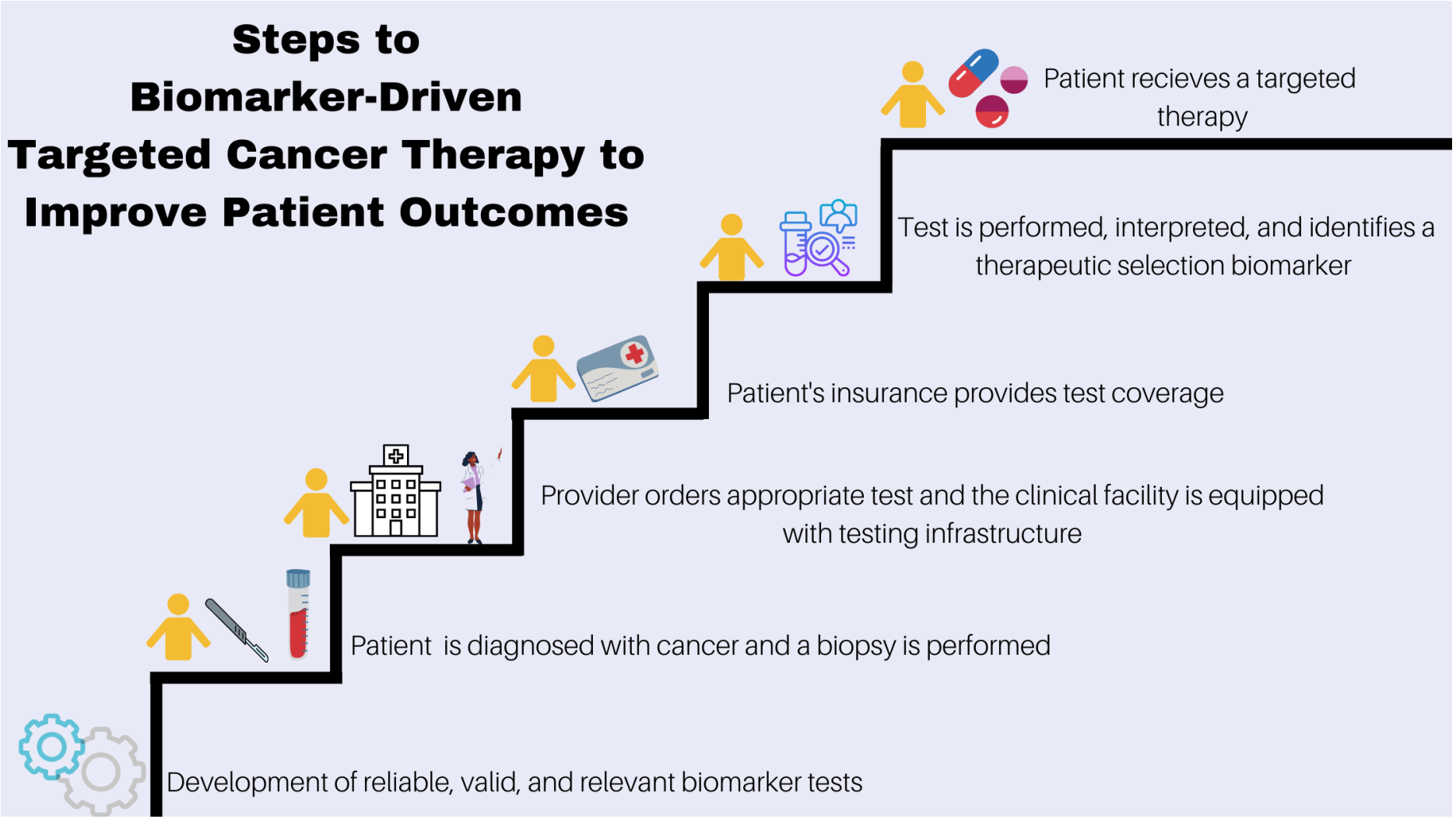
Cancer clinical trials are increasingly driven by biomarkers and the development of targeted therapies



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.

Barriers to Biomarker Testing



Barriers to Cancer Biomarker Testing

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

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

5 cycles of chemoimmunotherapy. Causes shortness of breath.

Insurance only covers single marker testing for ALK and EGFR. No mutations found.

ER visit for shortness of breath. CT scan shows tumor continues to grow.

Rebiopsy to test for another single marker, **RET.** No mutation found.

Starts combination chemotherapy. Must **stop working due to side effects.**

Switches to another chemotherapy due to toxicity. **After 5 cycles, a CT scan shows the tumor continues to grow.**

Rebiopsy and single marker test for ROS1 **reveals ROS1 mutation.**

Starts targeted oral therapy. **Disease stabilizes.**

With Comprehensive Biomarker Testing

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

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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

Why Disease Agnostic?

Biomarker testing applications extend beyond oncology

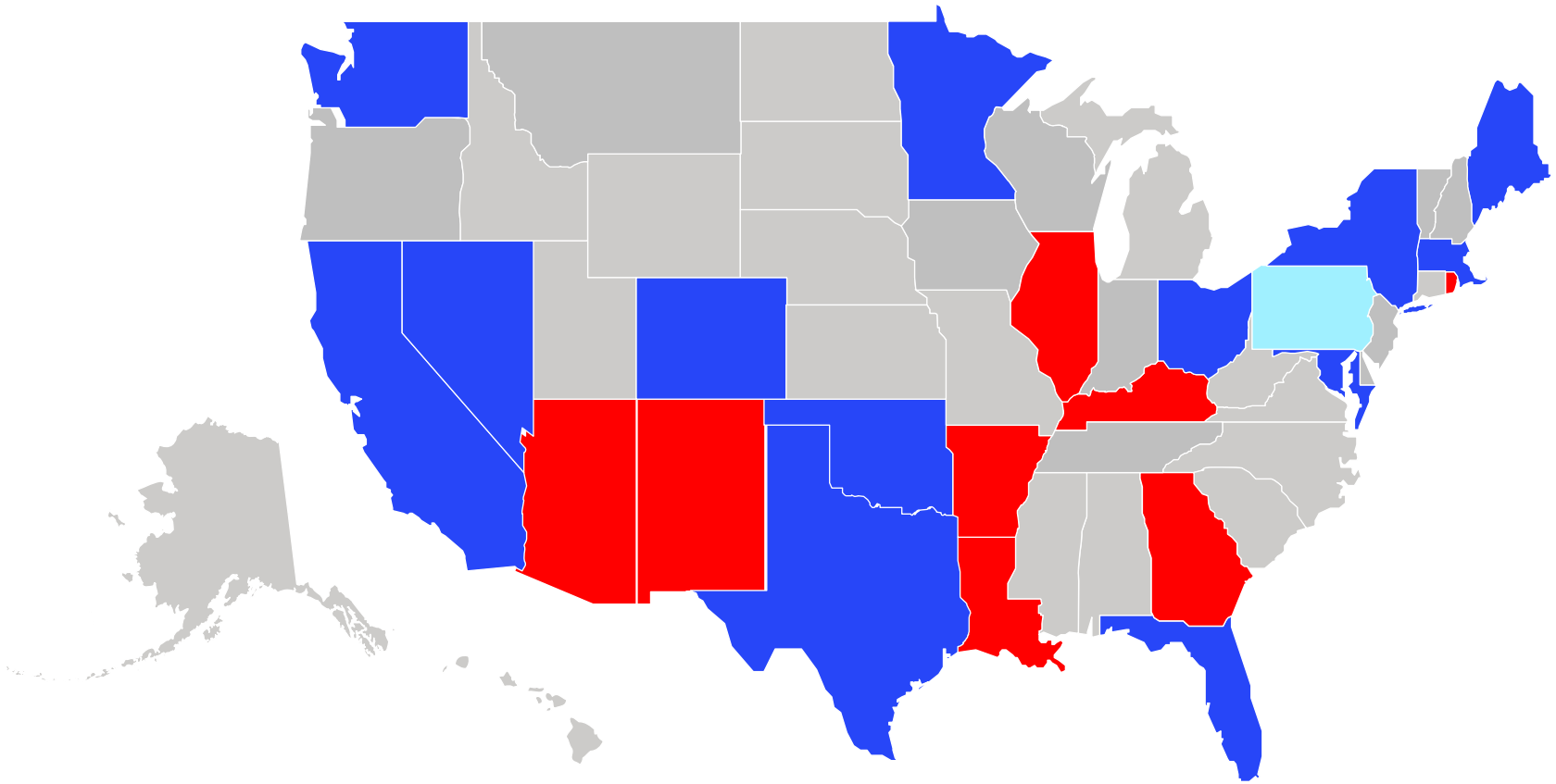
- Biomarker testing is increasingly important for the treatment of diseases including:
  - Arthritis and other autoimmune conditions
  - Rare diseases

Research is happening in many other areas including Alzheimer's, other neurological conditions, and cardiology.

Cancer patients and survivors have high rates of comorbidities

- Substantial progress has been made in the fight against cancer in recent decades, resulting in a 33% reduction in the cancer death rate since its peak in 1991.
- As patients are living longer, and some cancers become more of a chronic condition, cancer patients are often living with one or more comorbidities.
  - Most common comorbidities include diabetes, cardiac conditions (COPD, congestive heart failure, cerebrovascular disease), peripheral vascular disease), renal failure, and rheumatological conditions.
  - A recent study found that nearly two-thirds of patients diagnosed with colorectal cancer, lung cancer, or Hodgkin's lymphoma had at least one comorbidity at the time of their diagnosis, and about half of patients had multiple comorbidities.

Legislation to Expand Access to Biomarker Testing



	Legislation introduced
	Legislation enacted
	Legislation passed
	Legislation expected

Legislation enacted: AZ, IL, LA, RI, KY, NM, AR*, GA
Legislation passed (2023 session): MD
Legislation expected in 2023: CA, CO, FL, MA, ME, MN, NV, NY, OH, OK, PA, TX, WA
*commercial coverage only

How will state legislation help?

- Biomarker testing helps connect patients with the most effective treatment for their cancer and avoid treatments that will be ineffective.

Currently, most plans cover some biomarker testing for some patients.

- Personalized treatments are helping cancer patients live longer and better.

Without action to improve access to biomarker testing, some patients will be left behind from the latest advancements in treatment.

- Legislation applies to state-regulated insurance plans, including Medicaid
- Disease & stage agnostic

Biomarker testing should be covered and reimbursed by public and private payers when supported by clinical practice guidelines or peer-reviewed scientific evidence.

Broad Patient & Provider Support for Biomarker Testing

Didactic Q & A

Case Presentation:
UT Southwestern

UT Southwestern Medical Center

Sheena Bhalla, MD

Assistant Professor

Internal Medicine – Hematology/Oncology

UT Southwestern

Summary of Case

- 72 year old male with CAD s/p PCI, HFrEF, and active smoker initially diagnosed with stage 1a LUL lung adenocarcinoma s/p SBRT (not surgical candidate). He received VA authorization to receive RT at UTSW.

- Surveillance CT chest showed enlargement of several nodes in the AP window area. PET/CT demonstrated interval decrease in the size and FDG uptake of previously seen LUL mass, suggestive of favorable treatment response. New mediastinal and left hilar lymph nodes with moderate FDG uptake, indeterminate for reactive nodes versus metastatic disease.

- He underwent EBUS with biopsy of 4L showing lung adenocarcinoma. 11L without carcinoma.

- Completed chemoRT for mediastinal recurrence. He received VA authorization to receive medical oncology care at UTSW.

- He proceeded with consolidative durvalumab after chemoRT.

Summary of Case Continued…

- He underwent thoracentesis of left pleural effusion. Cytology of pleural fluid c/w lung adenocarcinoma, poorly differentiated, signet ring type.

- After seeing progression to metastatic disease on CT chest, I sent tissue from 4L for tissue NGS. Returned as QNS. I also sent plasma NGS at this time.

- My nurse received message from Guardant that we needed authorization number from VA Triwest for billing. My nurse had not run into this issue before for our VA patients. She contacted local account executive, who was also unfamiliar with this issue but discussed further with her finance team.

- After discussions between my nurse and Guardant, initial VA authorization to receive medical oncology care at UTSW was sufficient for testing to be completed and covered by Triwest.

- Patient's plasma NGS showed KRAS G12D and STK11 mutations. While not "targetable alterations," concurrent KRAS and STK11 mutations are associated with immunotherapy resistance and poor prognosis. This knowledge guided discussions regarding treatment and prognosis.

Case Presentation Discussion

Specific Questions to the Group	
Q1	If your team runs into issues regarding insurance coverage for NGS testing, does your team know who to reach out?
Q2	How has your experience been working with regional representatives for NGS companies?

Wrap-Up & Post-Session Poll Questions

A Few Reminders:

Next ECHO Session: June

Next Didactic Presenter: TBD

Materials and Resources will be made available.
All resources will be available on the [ACS ECHO Website]

Spokes: Interested in scheduling your Case Presentation?
Let us know.
Faculty: All future case presentations will be shared with you at least 24-hours in advance

Additional Feedback on Today's Session? Tell us in the Post Session Feedback Forum (URL in chat box)

Questions: Contact korey.hofmann@cancer.org

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THANK YOU!

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