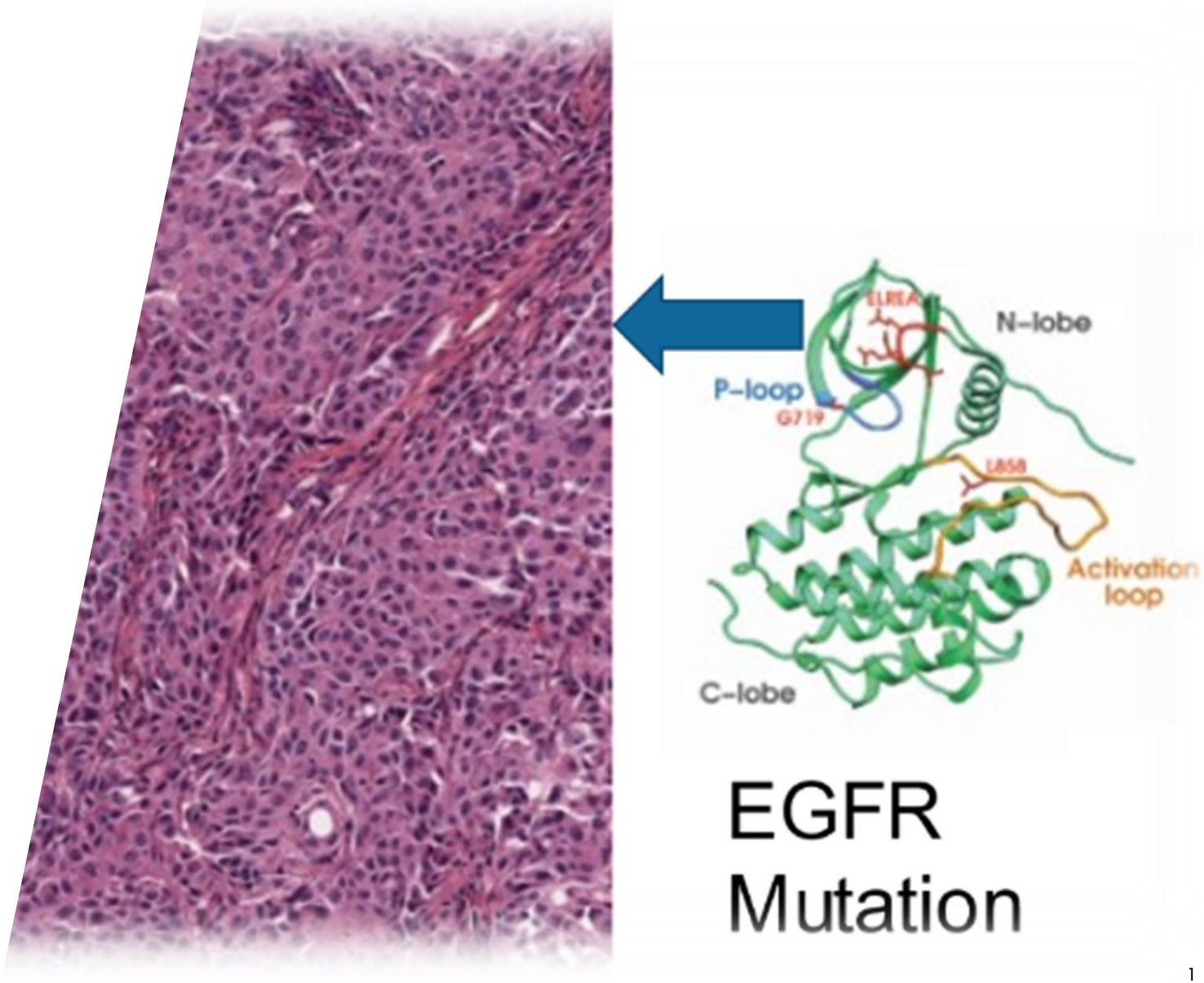
Welcome!

Before we begin…

Today's session will be recorded

Please add your name and organization in the chat



Wednesday, April 24, 2024 • 2:00 – 3:00 PM EDT

Lung Cancer Biomarker Testing ECHO Year 3

Session 4: Navigating Insurance Complexities

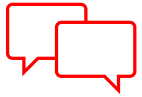
Welcome to Session 5 of the

Lung Cancer Biomarker Testing ECHO Year 3

Each ECHO session will be recorded and will be posted to a publicly-facing website

You will be muted with your video turned off when you join the call. Use the buttons in the *black* menu bar to unmute your line and to turn on your video. **If you do not wish to have your image recorded, please turn OFF the video option**.

Today's materials will be made available on our ACS ECHO website, https://echo.cancer.org.



Please type your full name, the full name of your organization, and e-mail in the chat box

This ECHO session takes place on the Zoom platform. To review Zoom's privacy policy, please visit zoom.us/privacy

Questions about Zoom? Type in the chat box @Mindi Odom

The Biomarker ECHO series is made possible with funding provided by:

Additional thanks to Foundation Medicine and founding sponsor, Amgen

Have a question? Don't wait to ask! Feel free to enter in the **Chat** at any time.

Today's Agenda

1 **Housekeeping, Agenda Preview, and Introductions**
10 minutes

2 **Didactic Lecture: Navigating Insurance Complexities**
Hilary Goeckner & Cori Chandler
10 minutes

3 **Didactic Q/A**
10 minutes

4 **Case Presentation: Andrew Liman, MD**
5 minutes

5 **Case Presentation Recommendations and Discussion**
15 minutes

6 **Post Session Poll & Wrap Up**
5 minutes

Your ECHO Support Team

Korey Hofmann, MPH
ECHO Lead
Program Manager, National Lung Cancer Roundtable

Mindi Odom
Director, Project ECHO
Your ECHO Co-Lead

Beth Graham, MPH, CHES
Program Manager, Project ECHO

Jennifer McBride, PhD
Senior Data & Evaluation Manager

Donoria Evans, PhD, MPH
Director, Data and Evaluation,
National Roundtables and Coalitions

Introductions

Meet Our Lung Cancer Biomarker Testing ECHO HUB Subject Matter Experts (SMEs)

Millie Das, MD
Chief, Oncology
VA Palo Alto Health Care System
Clinical Associate Professor
Stanford University

Aakash Desai, MBBS, MPH
Assistant Professor of Medicine
O'Neal Cancer Center
University of Alabama, Birmingham

Grace Dy, MD
Professor of Oncology
Roswell Park Comprehensive Cancer Center

DuyKhanh Pham "Mimi" Ceppa, MD, FACS
Associate Professor of Thoracic Surgery
Indiana University School of Medicine

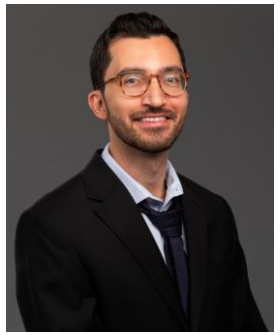
Matthew Facktor, MD
System Chief, Thoracic Surgery
Geisinger Health

Adam Fox, MD
Assistant Professor
Medical University of South Carolina

Jason Merker, MD, PhD
Associate Professor, Department of Pathology and Laboratory Medicine & Genetics
University of North Carolina Lineberger Comprehensive Cancer Center

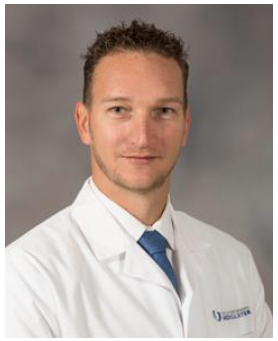
Introductions

Meet Our Lung Cancer Biomarker Testing ECHO HUB Subject Matter Experts (SMEs)



Koosha Paydary, MD, MPH, MSc
Assistant Professor, Department of Internal Medicine
Rush University

Catherine R. Sears, MD
Associate Professor of Medicine, Division of Pulmonary, Critical Care, Sleep and Occupational Medicine
Indiana University School of Medicine
Simon Comprehensive Cancer Center



Michal Senitko, MD
Assistant Professor
The University of Mississippi Medical Center

Gerard Silvestri, MD, MS
Hillenbrand Professor of Thoracic Oncology
Medical University of South Carolina

Heather Wakelee, MD (Ad Hoc)
Professor of Medicine and Chief of the Division of Oncology,
Stanford University School of Medicine
Deputy Director, **Stanford Cancer Institute**

Ignacio Wistuba, MD
Professor and Chair, Department of Translational Pathology
The University of Texas MD Anderson Cancer Center

Welcome to our Participant Learning Sites

ALABAMA

- Mobile Infirmary
- O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham
- University of South Alabama Health, Mitchell Cancer Institute

CALIFORNIA

- Comprehensive Cancer Center at Desert Regional Medical Center
- Fresno VA Medical Center
- Harbor UCLA
- Providence St. Joseph Health
- Sharp Healthcare

INDIANA

- Ascension St. Vincent Indianapolis
- Deaconess Hospital, Inc.
- Franciscan Alliance Burrell Cancer Center Crown Point
- Methodist Hospitals

NORTH CAROLINA

- Cone Health Medical Group/Cone Health Cancer Center
- Novant New Hanover Regional Medical Center
- UNC Caldwell McCreary

Bruce E. Johnson, MD, FASCO
Dana-Farber/Harvard Cancer Center
Lung Cancer Program
Senior Consultant, Dana-Farber Cancer Institute

Lung Cancer Biomarker Testing ECHO
FACILITATOR

Hilary Goeckner & **Cori Chandler**
State & Local Campaigns
ACS **Cancer Action Network**

Session 5 Didactic:
Navigating Insurance Complexities

American Cancer Society Cancer Action Network℠

Biomarker Testing 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 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)

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.

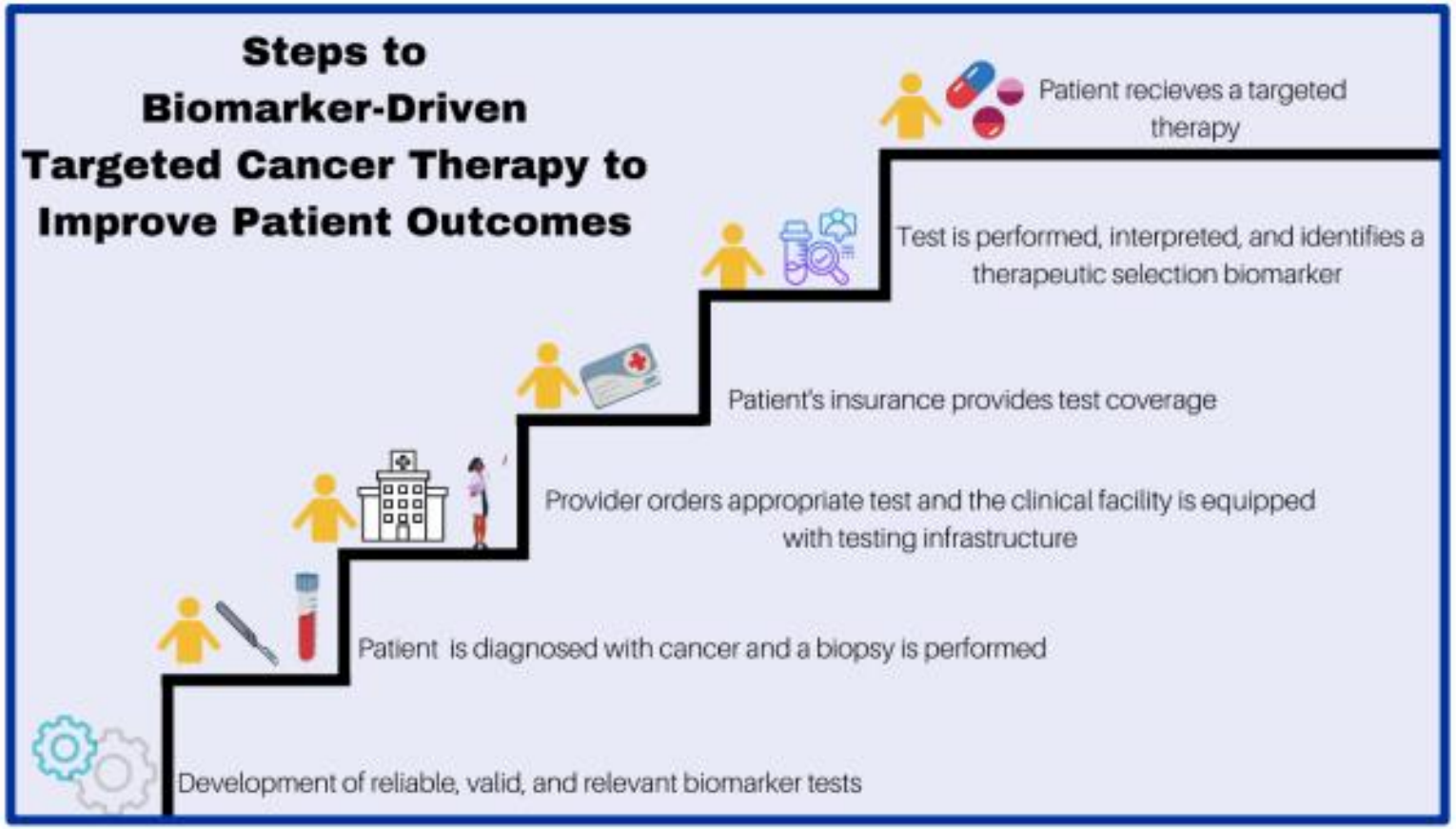
Who is getting tested?

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.

Many barriers to optimal use



Improving Access to Biomarker Testing: Advancing Precision Medicine in Cancer Care. ACS CAN. September 2020.

Barriers: Insurance

Coverage of tests differs greatly across payers

- Most plans are covering some biomarker testing for some patients.
- 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.**

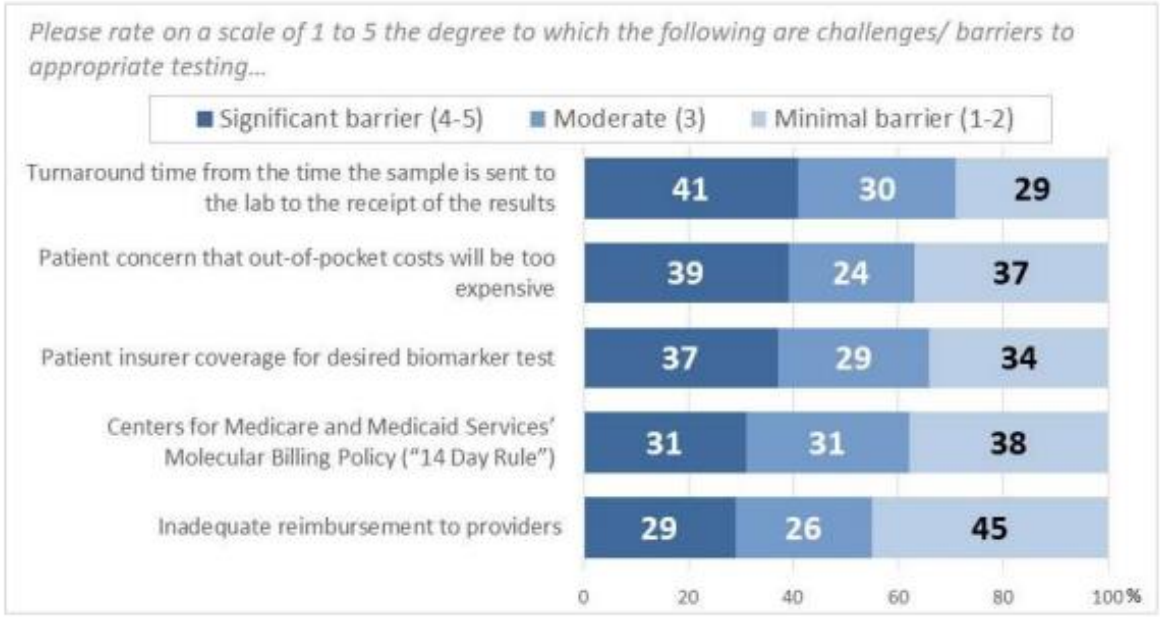
Wong, W., et al. (2022) *Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors.*

Barriers: Insurance

Provider experiences

- National survey of oncology providers found insurance coverage and cost concerns are top barriers to appropriate use of biomarker testing for their patients
  - ➢ 66% report “patient insurer coverage for desired biomarker test” is a significant (37) or moderate barrier.
  - ➢ 63% report “patient concern that out-of-pocket costs will be too expensive is a significant (39) or moderate barrier.

- Prior authorization delays, physician education, decision making, and turnaround time for results are also challenges.



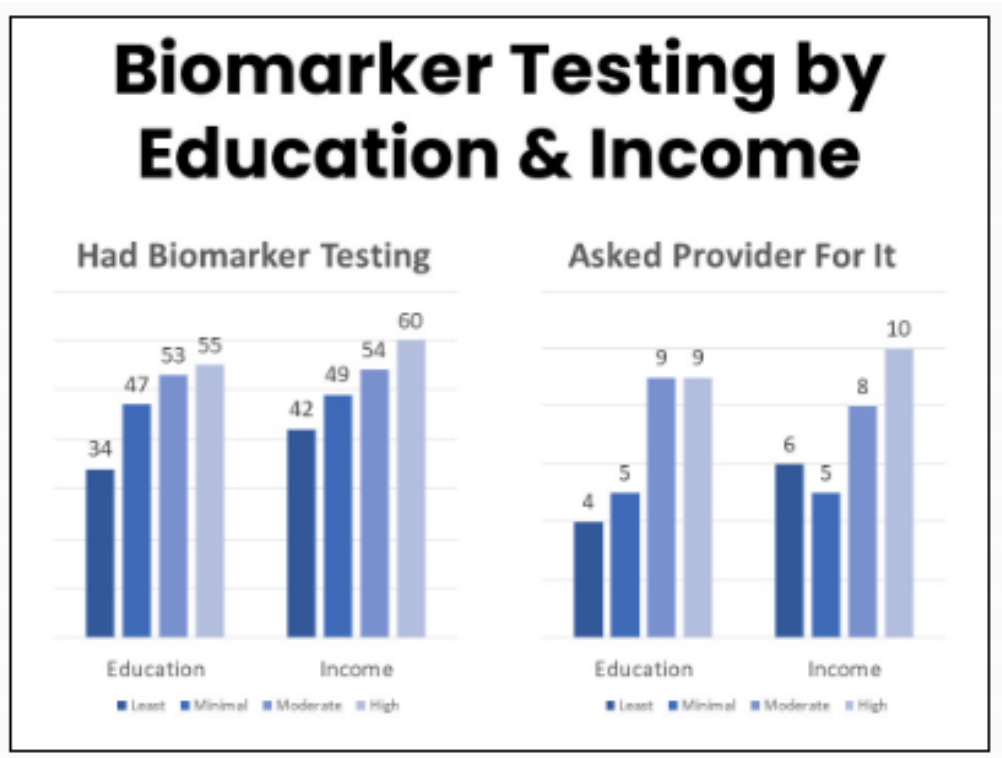
Understanding Provider Utilization of Cancer Biomarker Testing. ACS CAN. Dec. 2021.

Barriers: Insurance

Patient experiences

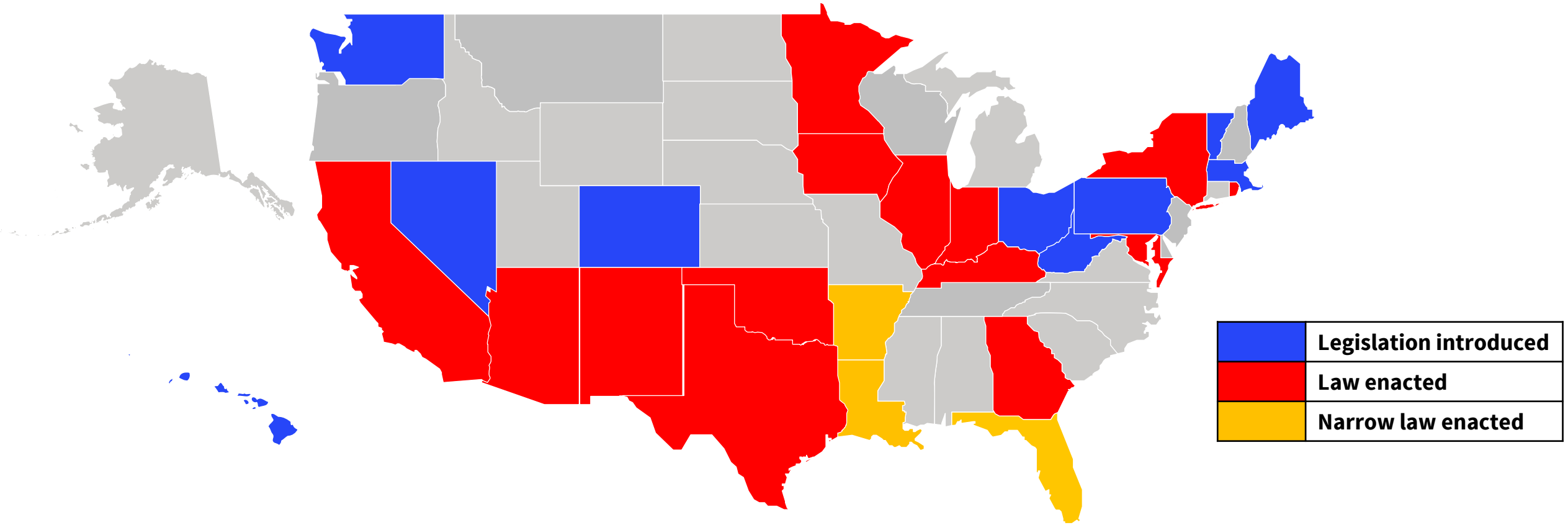
- October 2023 *Survivor Views* survey on biomarker testing found more patients (49%) are receiving biomarker testing than in 2020 (39%).
  - **Half of patients tested report it allowed them to avoid unnecessary treatments or procedures.**
  - **Three percent were able to enroll in a clinical trial because of their results.**

- Disparities persist by income, education, insurance type.
  - Of those who did not receive biomarker testing, 9% report lack of insurance coverage of needed testing as the reason.
- Patients who received testing overwhelmingly agree it helped their providers better treat their cancer.



Survivor Views. ACS CAN. October 2023.

Legislation to Expand Access to Biomarker Testing



Legislation enacted: AZ, AR*, CA, GA, IL, IN, KY, LA*, MD, MN, NM, NY, OK, RI, TX
Legislation introduced: CO, HI, MA, ME, NV, OH, PA, VT, WA, WV
Awaiting signature: FL**, IA

Updated 4/16/2024

* Private plans only **public plans only

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
  - FDA recently approved test for risk of preeclampsia

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.

Pushback and questions

Does not

- Require coverage of testing for screening purposes
- Require coverage of unproven or unnecessary testing
- Require coverage of biomarker testing for every cancer patient
- Set reimbursement levels

Limitations

- Only applies to state-regulated plans
- OOP costs may still be a barrier
- Addresses coverage. Additional work ongoing to address other barriers.

Questions about costs to states, payors

- Milliman study projects premium impact of $0.08-0.51 PMPM
- Growing evidence about cost avoidance, more efficient care delivery.

The landscape of biomarker testing coverage in the United States. Gabriela Dieguez and Jennifer Carioto. Milliman. February 2022

American Cancer Society Cancer Action Network℠

Learn more:

fightcancer.org/biomarkers

American Cancer Society Cancer Action Network℠

Ongoing Legislative and Education Work

Laying the groundwork

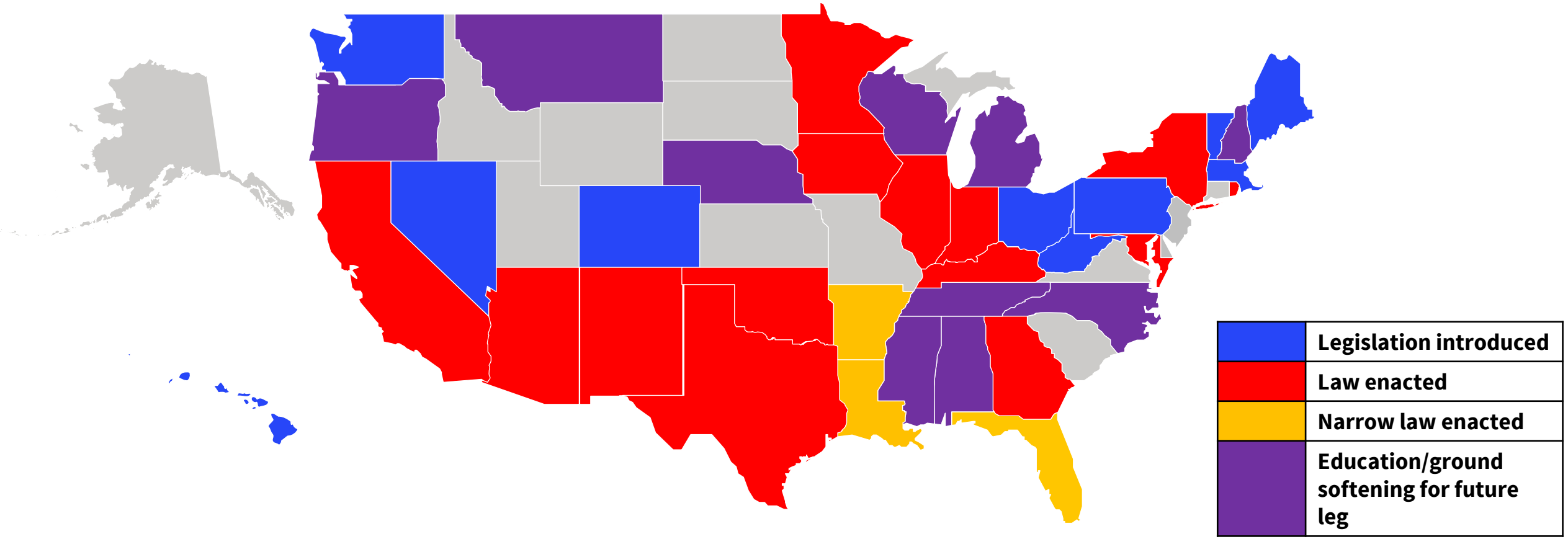
Efforts to educate on the issue and build momentum towards bill introduction makes for a more successful campaign:

- Build strong, diverse coalition, including non-oncology stakeholders
- Collect patient stories
- Educate lawmakers/volunteers

Continuing these strategies after bill introduction:

- Keep coalition engaged, informed and involved in work
- Utilize patient stories
- Meeting with lawmakers to secure support
- Coalition advocacy events with volunteers
- Engage media

Legislation to Expand Access to Biomarker Testing



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Legislation introduced: CO, HI, IA, MA, ME, NV, OH, PA, VT, WA, WV
Awaiting signature: FL**, IA

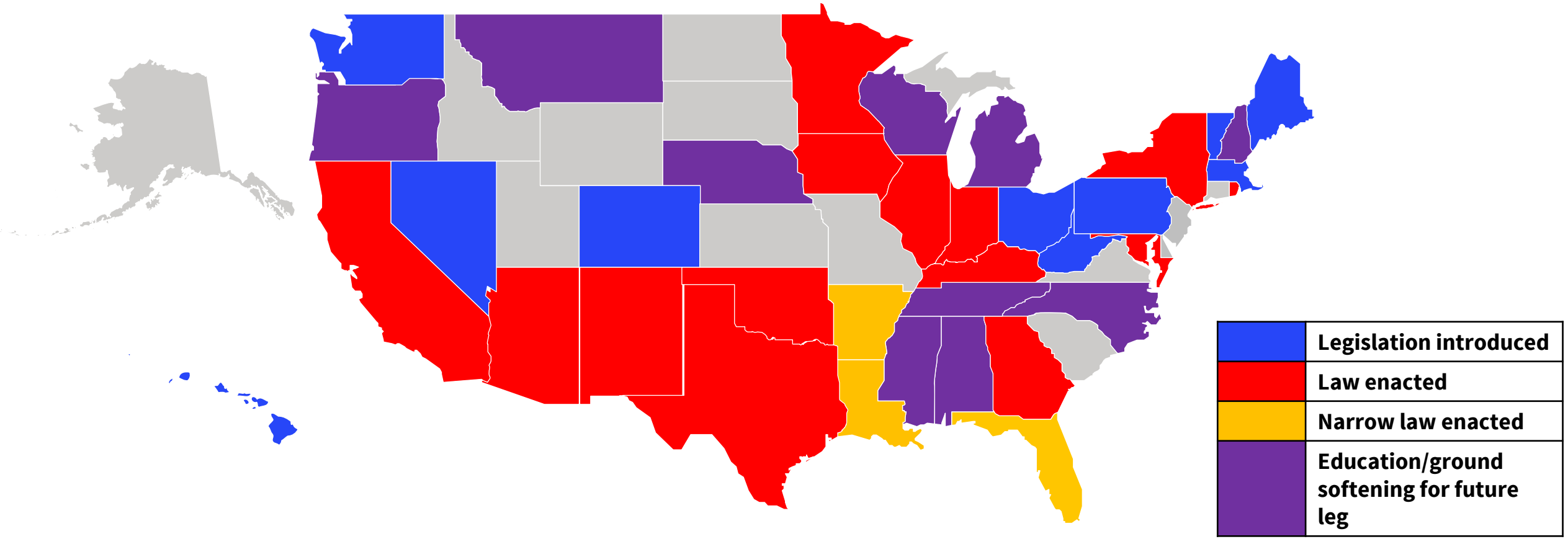
Updated 4/16/2024

* Private plans only **public plans only

American Cancer Society Cancer Action Network℠

Supporting Implementation in States with Biomarker Testing Laws

Legislation to Expand Access to Biomarker Testing



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Legislation introduced: CO, HI, IA, MA, ME, NV, OH, PA, VT, WA, WV
Awaiting signature: FL**, IA

Updated 4/16/2024

* Private plans only **public plans only

Supporting implementation

Who is impacted?

- State regulated private plans, Medicaid, state employee health plans
- Effective dates vary (January 2021-January 2025)
- Purpose of testing and evidence

Educate providers and institutions

- What should now be covered
- What evidence may be required

Advocate to payers and regulator

- Institution, testing companies work with insurers to update relevant policies
- Appeal denials on testing that should be covered
- File complaints with state insurance commissioner

Thank You

Open Discussion: Questions & Answers

Andrew Liman, MD
Fresno VA Medical Center

Session 5
Case Presentation

Lung Cancer with MET exon 14 amplification

Andrew Liman, MD
Section Chief, Hematology/Oncology, VACCHCS
Assistant Clinical Professor of Medicine, UCSF Fresno

Case of Lung cancer

- The patient is a 83 Y/M with h/o HTN, Hyperlipidemia, COPD, GERD, diverticulosis, DJD presented with pathologic fracture of LEFT femur in Sept 2019. CT showed incidental 5 cm left lower lobe lung mass, mediastinal LNs and small bilateral lung nodules. Stage IV, cT3N2M1.
- Patient underwent ORIF of the left femur at Stanford on 9/26/2019. No malignancy was found in the bone. EBUS and biopsy of mediastinal LN 4R, 4L, 7 on 10/10/2019 revealed poorly differentiated carcinoma, NSCLC with sarcomatoid differentiation. The tumor cells were positive for pankeratin, CK7, CD68, calretinin (weak), while negative for TTF-1, p40, WT1, D2-40, and SOX-10. PDL1 TPS 100%.
- MRI brain showed 10mm right frontal metastasis with edema. PET revealed right adrenal, pancreatic tail metastasis, abdominal LNs. Pt received SBRT to brain in Visalia with improvement on subsequent scan. Pt also received RT to the left hip.
- Patient received carboplatin, pemetrexed, and pembrolizumab. PET 6/2020 showed partial response. Cycle 4 was held due to pt developed myositis with Increase ALT/AST to 4000s. Treated with prednisone. Pembrolizumab was discontinued. Continue only on maintenance pemetrexed.

Case continue

- Discussed in our Tumor board meeting
- To start targeted agent based on MET exon 14 amplification.
- FOUNDATION MEDICINE: Foundation One CDX 2/19/2020:

Biomarker Findings

Microsatellite status - MS-Stable
Tumor Mutational Burden - 8 Muts/Mb

Genomic Findings

For a complete list of the genes assayed, please refer to the Appendix.

MET **exon 14 splice site (D1010H), amplification**
BRAF **amplification**
CDKN2A/B **loss**
CREBBP **I1301fs*12**
DIS3 **amplification**
KEL **amplification**
MTAP **loss exons 2-8**
TP53 **R158S**

6 Disease relevant genes with no reportable alterations: *ALK, EGFR, ERBB2, KRAS, RET, ROS1*

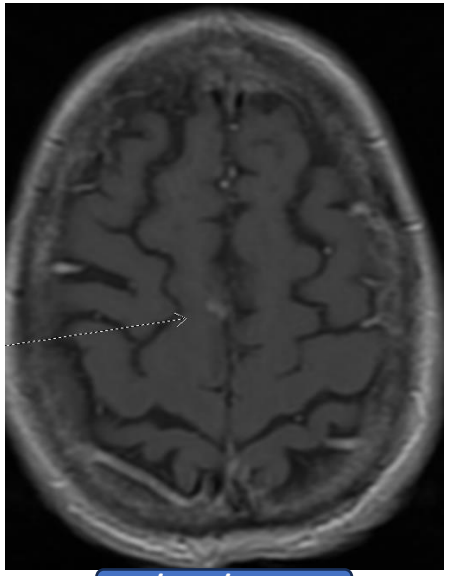
BIOMARKER FINDINGS	ACTIONABILITY	
Microsatellite status - MS-Stable	**No therapies or clinical trials.** see Biomarker Findings section	
Tumor Mutational Burden - 8 Muts/Mb	**No therapies or clinical trials.** see Biomarker Findings section	
GENOMIC FINDINGS	**THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)**	**THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)**
MET - exon 14 splice site (D1010H), amplification	Crizotinib 2A	Cabozantinib
10 Trials *see p. 10*		

Case continue

- PET scan 10/2022 showed disease progression. Patient has MET exon 14 amplification. He was started on capmatinib 400 mg po BID on 12/2020.
- Patient developed anasarca and LE edema. Started on furosemide. Decreased dose of capmatinib to 200 mg BID. PET scan 11/2021 revealed improvement LLL lung mass with stable adrenal nodule.
- Replacement of left ORIF due to new fracture line at Stanford Dec 2021. Removal of hardware and re-cemented.
- PET 8/2022 showed resolution of the LLL lung nodule but a new LLL nodule 1.6 x 1.2 cm. Tumor board recommended LLL nodule biopsy. IR biopsy 9/2022 insufficient tissue for diagnosis.
- MRI brain 7/2022 stable minimal residual brain lesion. Persistent left hip pain and left LE edema. Increased furosemide dose to 40 mg.
- Pt underwent third surgery (left hip revision surgery) in March 2023 and prescribed IV antibiotic at home. Cefpodoxime for 6 months.
- PET scan 3/2023 increasing size LLL lung nodule. RUL lung nodule, non-specific.
- PET scan 9/2023 showed unchanged RUL lung nodule, LLL stable, no other FDG avidity
- PET scan Jan 2024 revealed increase size LLL nodule to 2 cm with FDG increased to from 4.6 to 6.1. Tumor board recommend SBRT. Pt completed SBRT in March 2024.
- Continue capmatinib 200 mg BID. Plan for f/u PET scan.

Case continue

MRI brain



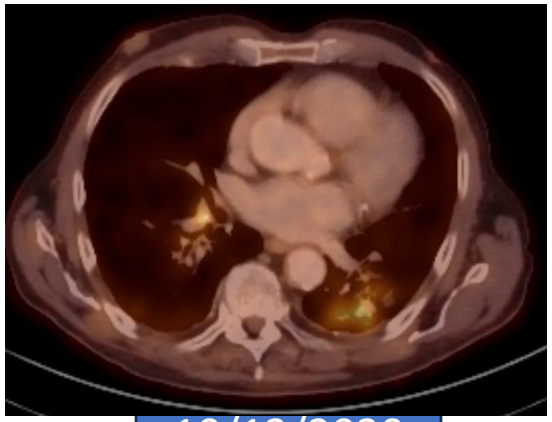
2/26/2021

PET scan 1/3/2024:

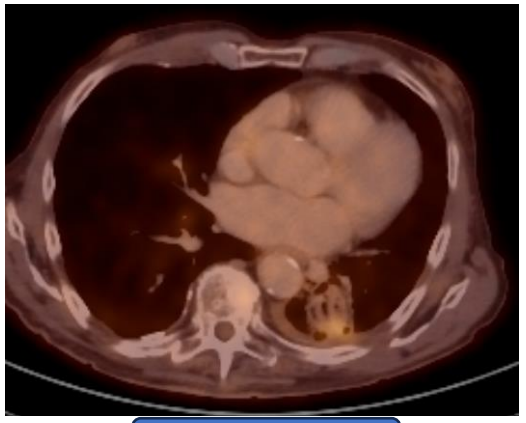
Impression:

1. **Interval increase in size and activity of the nodule in the left lung base suggest progression of disease. LLL nodule 2.0 cm with 6.1 SUVmax.**
2. **Stable semisolid nodular density in the RUL with low grade activity, scarring**
3. **Mild uptake in the right hilar LN is no longer apparent**
4. **No evidence of regional LN mets or distant metastasis**
5. **Bilateral pleural effusions are unchanged.**

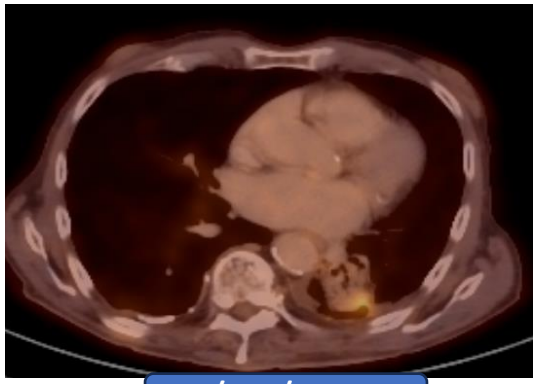
PET scans



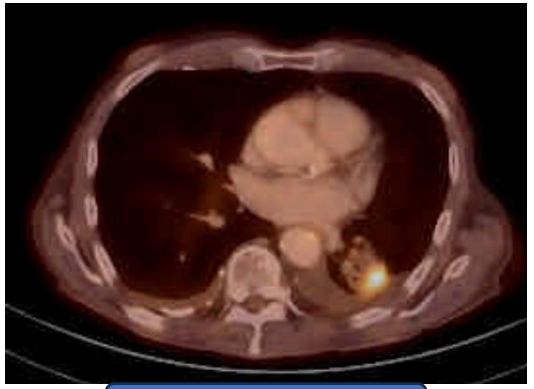
10/12/2020



8/10/2022



3/14/2023



1/3/2024

Molecular Testing coverage at the VA

- NPOP has an agreement with vendors (Neogenomic CDx and Tempus) to cover all biomolecular testing for cancer veterans.
- There is a guideline which markers need to be tested, based on NCCN
- Portal has been linked in the VA system.
- Physicians, pathologists and nurses are able to put orders for somatic or liquid testing.
- Results usually takes about 2-3 weeks, sometime 4 weeks.
- Providers are able to see results in website.

Eligibility	Test Category	Test Type	Recommended Vendors	NPOP Coverage	Specimen Type
Stage IIA and Higher NSCLC	IHC	PD-L1 expression by IHC using 22C3 antibody	Tempus Foundation Medicine Local Vendor	Yes (when ordered with CGP) Yes (when ordered with CGP) No	Tumor Tissue
Stage IIA and Higher NSCLC Non-Squamous	Somatic NGS*	DNA and RNA-based comprehensive genomic profiling (CGP)	Tempus Foundation Medicine	Yes Yes	Tumor Tissue, Blood
Stage IV Squamous Never/Light Smoker, Mixed Histology, or Small Specimen Size	Somatic NGS*	DNA and RNA-based comprehensive genomic profiling (CGP)	Tempus Foundation Medicine	Yes Yes	Tumor Tissue, Blood
* Somatic NGS testing should adequately cover point mutations, small insertion/deletion mutations, amplifications, and fusion oncogenes; at minimum testing should include coverage of EGFR, ALK, ROS1, RET, MET, BRAF, KRAS, NTRK1, NTRK2, NTRK3, and HER2					
** Tissue testing strongly preferred because it is the only method for RNA based testing. Liquid testing is suboptimal but acceptable only if adequate tissue cannot be obtained.					

Session 5 Case Study

Provided by: Andrew Liman, MD, VACCHCS
Focus: Patient

Discussion & Questions

- What is the optimal therapy for edema due to MET inhibitors?
- What is the lowest capmatinib dose that is still considered effective?
- If patient relapsed on this drug what is the next step/recommendation?

Case Summary

- Patient is an 83Y/M with metastatic poorly differentiated carcinoma (NSCLC) and MET exon 14 amplification in 2019. Patient received chemotherapy with carboplatin, pemetrexed and pembrolizumab also SBRT to the single brain metastasis.

- In 2022 developed disease progression, started on capmatinib 400 mg BID. Lung nodules have been stable with improvement, but patient developed LE edema treated with diuresis.

- Last PET scan in Jan 2024 shows worsening LLL nodule and patient received SBRT in March 2024. Patient continues to take capmatinib at reduce dose 200 mg BID until now.

Open Discussion: Questions & Answers

Session Reminders

Session 5 Slides, Recordings, & Resources will be made available within one week. All resources will be available on the **ACS ECHO Website.**

Register Today for **Session 6**

Friday, May 24, 2024

12:00 – 1:00 PM EDT

Topic: Patient Perspective, Program Wrap Up and Next Steps
Didactic Presenter: Donnita Butler
State Breakout Groups: Next Steps/Networking

Session #	Month	Date	Time (ET)	Didactic Topic	Didactic Presenter	Facilitator
~~0~~	~~December~~	~~Weds. 12/13~~	~~4:00 - 5:00pm~~	~~Series Kick-Off: Introduction to ECHO and Biomarker Testing Guideline Overview:~~	~~Mimi Ceppa, MD, Aakash Desai, MBBS, MPH, Hilary Goeckner~~	~~Bruce E. Johnson, MD, FASCO~~
~~1~~	~~January~~	~~Weds. 1/17~~	~~4:00 -5:00pm~~	~~Understanding the Barriers and Pathways to Lung Cancer Biomarker Testing~~	~~Millie Das, MD~~	~~Timothy Mullett, MD, MBA, FACS~~
~~2~~	~~February~~	~~Fri. 2/9~~	~~4:00 -5:00pm~~	~~Adequate Tissue for Sampling~~	~~Nichole Tanner, MD, MSCR~~	~~Bruce E. Johnson, MD, FASCO~~
~~3~~	~~March~~	~~Weds. 3/6~~	~~4:00 -5:00pm~~	~~Choice of Panel, Interpretation of Results and Next Steps~~	~~Ignacio Wistuba, MD~~	~~Timothy Mullett, MD, MBA, FACS~~
~~4~~	~~March~~	~~Weds. 3/27~~	~~4:00 -5:00pm~~	~~Improving Turnaround Time~~	~~Jason Merker, MD, PhD~~	~~Bruce E. Johnson, MD, FASCO~~
~~5~~	~~April~~	~~Weds. 4/24~~	~~2:00 - 3:00pm~~	~~Navigating Insurance Complexities~~	~~Hilary Goeckner & Cori Chandler~~	~~Bruce E. Johnson, MD, FASCO~~
6	**May**	**Fri. 5/24**	**12:00 - 1:00pm**	**Series Wrap Up and Next Steps**	**Patient speaker**	**Timothy Mullett, MD, MBA, FACS**

A Few Reminders

The last ECHO Session: May 24, 2024, 12:00-1:00 PM ET Topic: Program Wrap Up and Next Steps

Please *register now* for **Session 6** by using the QR code or the link in the chat.

Slides, Recordings, & Resources will be made available within one week. All resources will be available on the **ACS ECHO Website.**

Contact Korey.Hofmann@cancer.org

Please send us a high-definition logo for your system.

Contact Korey if you haven't received calendar invitation for **Session 6**.

Questions? Korey Hofmann | korey.hofmann@cancer.org or Mindi Odom | mindi.odom@cancer.org

Thank You