NATIONAL LUNG CANCER ROUNDTABLE

American Cancer Society

Project ECHO

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

Session Five: Navigating Insurance Complexities

Reminder: Please type your *name, email address* and *organization* in the chat box

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

Each ECHO session will be recorded and will be posted on echo.cancer.org

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 echo.cancer.org

Please type your name, email address and organization in the chat box

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

Remember: Do NOT share any personal information about any patient

Questions about Zoom? Type them in the chat box or message

American Cancer Society

Project ECHO

Today's Agenda

01 **Agenda Preview & Introductions** (10 min)

02 **Didactic Presentation:** (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)

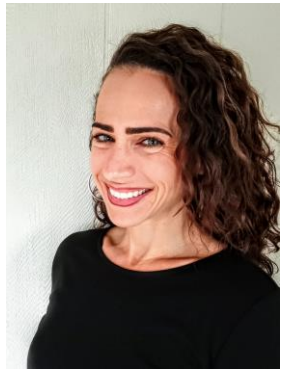
This ACS/NLCRT Lung Cancer Biomarker Testing ECHO series is made possible by funding provided by:

Additional thanks to Foundation Medicine

MEET OUR EASTERN COMBINED HUB TEAM

Korey Hofmann, MPH
American Cancer Society
National Lung Cancer Roundtable
ECHO Coordinator

Allison Rosen
American Cancer Society
ECHO Tech Coordinator



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American Cancer Society
Florida ECHO Coordinator

Shauna Shafer
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South Carolina ECHO Coordinator

Molly Black, MPH
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Annika Dean
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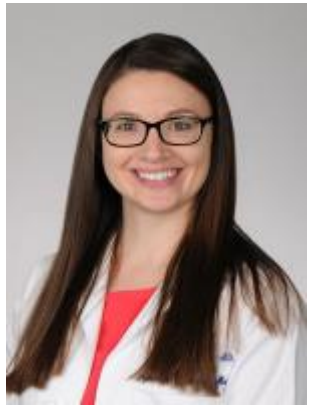
MEET OUR SC ECHO HUB

Adam Fox, MD

MUSC Health
Medical University of South Carolina

Jessica Forcucci, MD



MUSC Health
Medical University of South Carolina

Mariam Alexander, MD

MUSC Health
Medical University of South Carolina

Claudia Miller, BSN, RN, ONC, ONN-CG

MUSC Health
Medical University of South Carolina

Sean Callahan, MD

PRISMA HEALTH

Gerard Silvestri, MD, MS

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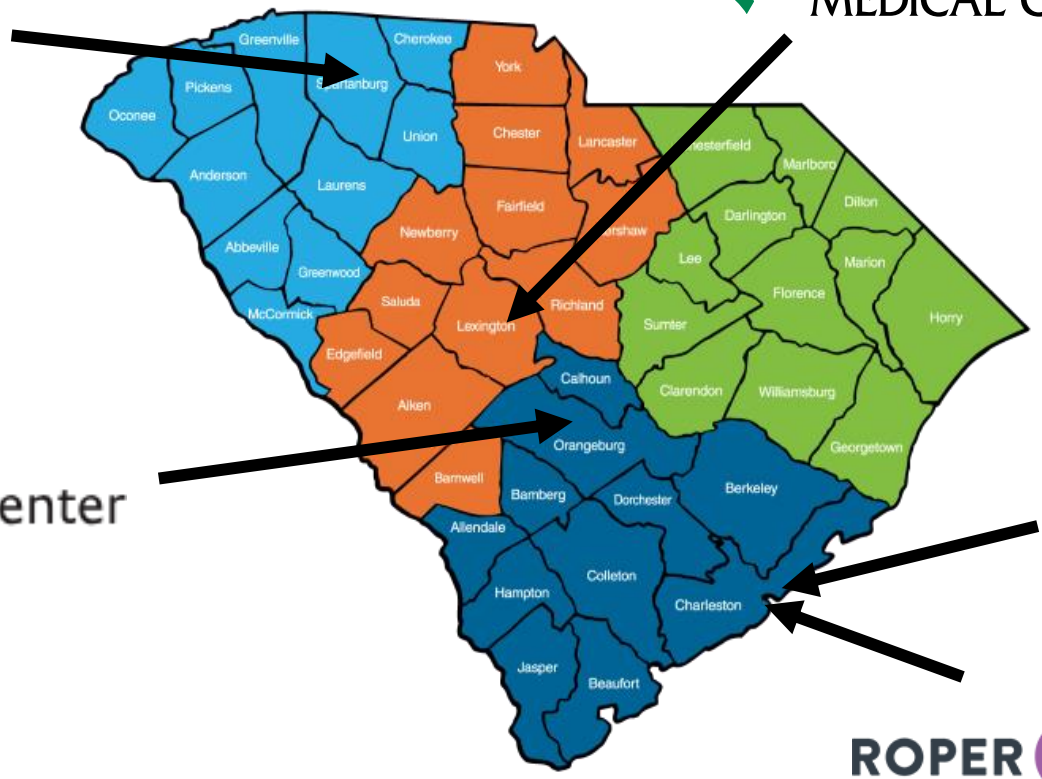
Kim Hale
ECHO Coordinator

Molly Black
ECHO Coordinator

MEET OUR SC CANCER CENTER SPOKE SITES

Spartanburg Regional Healthcare System

LEXINGTON MEDICAL CENTER



+rmc Regional Medical Center

VA U.S. Department of Veterans Affairs

ROPER ST. FRANCIS HEALTHCARE

One** Lead Person from Each Spoke Site to **Briefly** Say **Hello

SC LUNG CANCER BIOMARKER TESTING ECHO

SC ECHO SESSION SCHEDULE

Projected Month	Didactic	Combined Hub or State-Led	Didactic Presenter
10/[illegible]/2022 @ 8:00 AM ET	Series Kick-Off: Introduction to ECHO and Biomarker Testing Guidelines Overview	State-Led Session	Mariam Alexander, MD, PhD and Adam Fox, MD
10/24/2022 @ 1:00 PM ET	Understanding the Barriers and Pathways to Lung Cancer Biomarker Testing	Combined Hub*	Suresh Ramalingam, MD, FASCO
11/16/2022 @ 9:00 AM ET	Adequate Tissue for Sampling	Combined Hub*	Gerard Silvestri, MD, MS, FCCP
1/19/2023 @ 2:00 PM ET	Choice of Panel, Interpretation of Results, and Next Steps	Combined Hub*	TBD
2/22/2023 @ 1:00 PM ET	Improving Turnaround Time	Combined Hub*	Lynette Sholl, MD, FCAP
5/5/2023 @ 8:00 AM ET	Navigating Insurance Complexities	State-Led Session	**State Faculty**
5/26/2023 @ 8:00 AM ET	SC ECHO Session- Topic TBD	State-Led Session	**State Faculty**

Reminder: Please type your *name, email address* and *organization* in the chat box

Didactic Presentation:
Navigating Insurance Complexities

MUSC Health
Medical University of South Carolina

ADAM FOX, MD
PULMONOLOGIST

Disclosures

- I have personal stock ownership in Merck

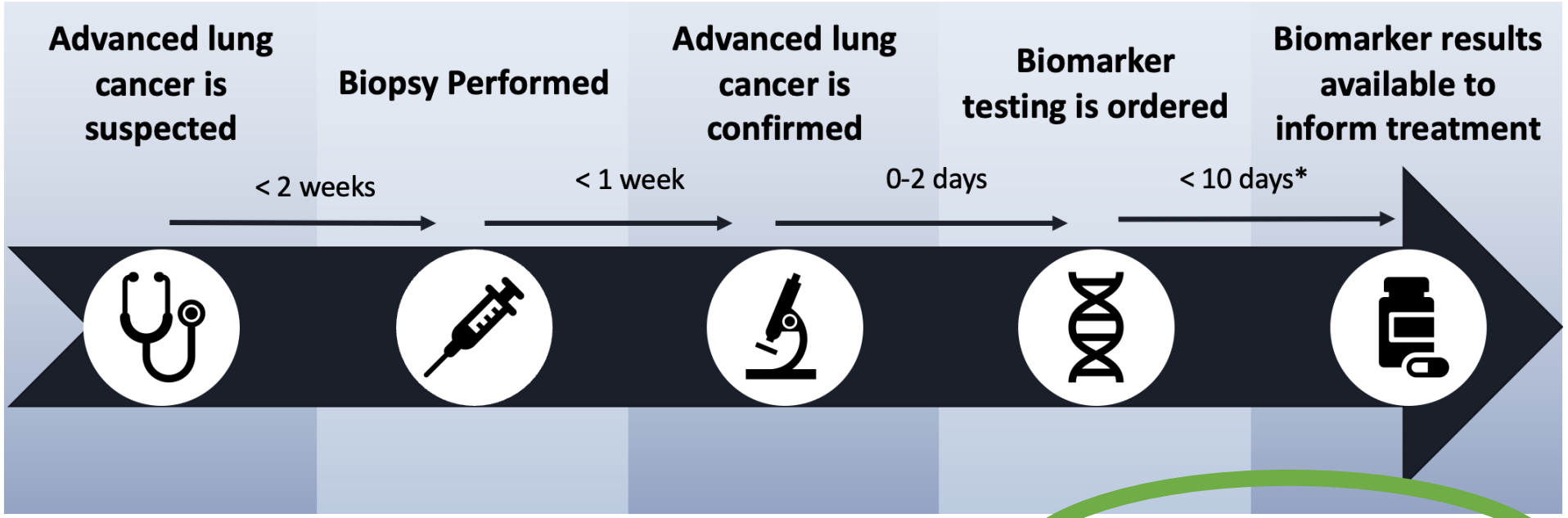
Disclaimer

- I am not an expert in the insurance reimbursement/payment process

ISSUES OF COST FOR PATIENTS WITH NSCLC

Patient access: Insurance & personal resources for initial evaluation

Cost of systemic treatments, radiation, etc.



Technology cost: EBUS, ROSE, trained personnel

Technologists and other support: time for navigation

Reimbursement, coverage, and costs of biomarker testing

Adapted from: Fox, AH et al. CA Cancer J Clin. 2023 Mar 1.

PERSPECTIVES OF COST

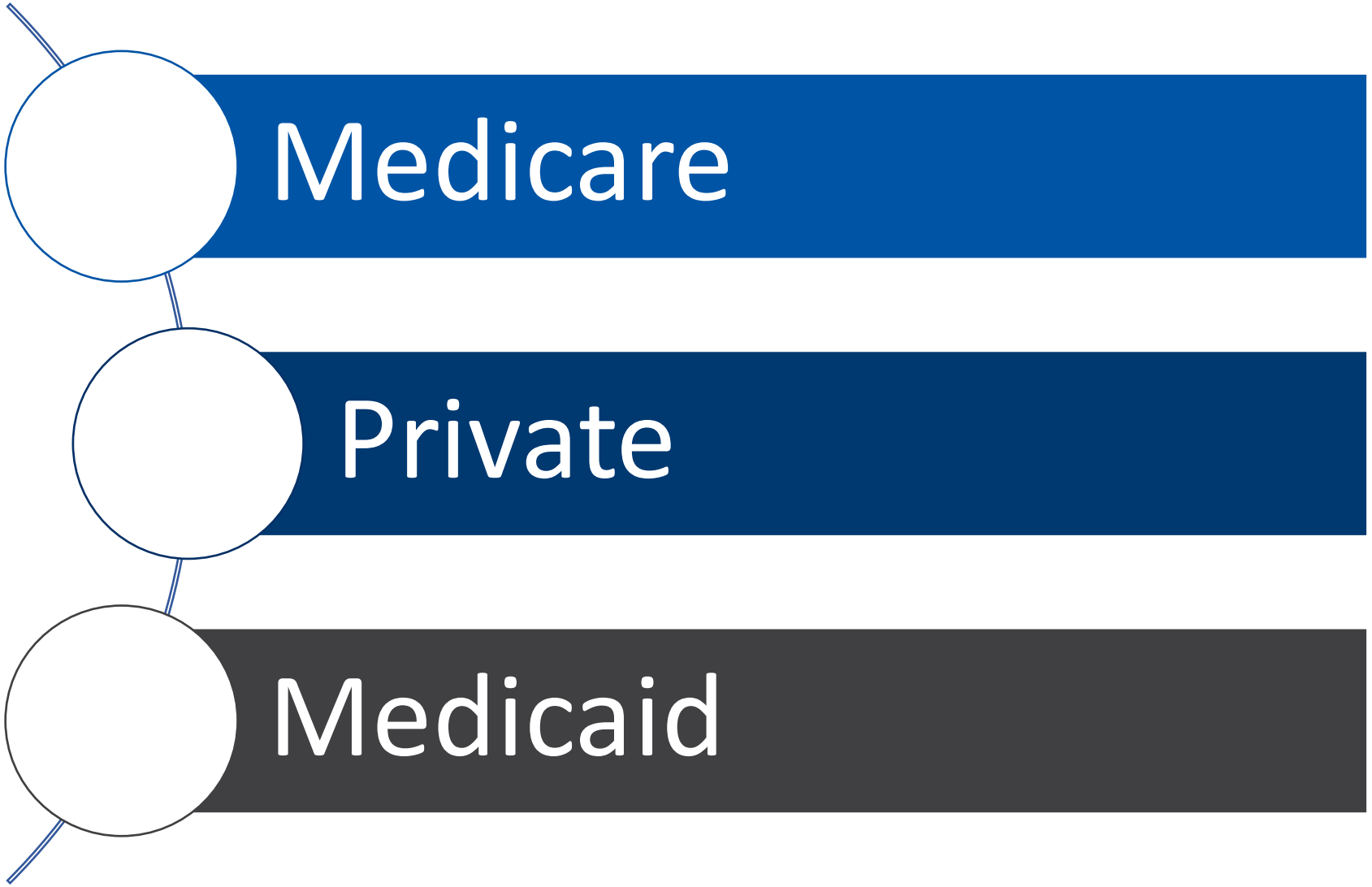
- **Payer perspective**
  - Rapidly changing landscape: Biomarkers, therapies, evidence, medical/technical complexity
    - How much testing is necessary to make decisions?
- **Health provider perspective**
  - Desire to avoid financial toxicity to patients
  - Time of providers and other team members ordering and fulfilling prior authorizations
    - Complicated by variable rules for coverage
  - Want as much information as possible (e.g., liquid + tissue, or testing for inclusion in clinical trials)
- **Patient perspective**
  - Co-pays, out-of-pocket costs, time, treatment effects

Sadigh G et al. Cancer. 2022 Aug 1;128(15):2865-2870

EVIDENCE OF COST SAVINGS/BENEFITS

- Model replaced single gene testing with NGS for advanced non-squamous NSCLC: each 10% increase in NGS = 2,627 life-years gained with a savings of $75/LYG
  - Lemmon CA, et al. JCO Precis Oncol. 2023 Jan;7:e2200294
- Modeling of NGS vs single gene strategies estimated costs savings to both public and private payers
  - Pennell, NA, et al. JCO Precis Oncol. 2019 Dec;3:1-9.
- Retrospective claims analysis and modeling of multi-gene tests vs single gene testing showed no appreciable differences in downstream costs and an estimated premium increase of $0.04 /plan /month
  - Wong W, et al. Future Oncol. 2023 Apr 18.

COVERAGE FOR BIOMARKER TESTING



MEDICARE BASICS: NATIONAL

Medicare Eligibility:

- ≥ 65 years old, ESRD, ALS, disability

Medicare Components:

- Part A - Hospital care, SNF, hospice (entitlement)
- Part B - ER, outpatient, radiation, and IV infusions (entitlement)
- Part C - Managed care
- Part D - Supplemental prescription plan

MEDICARE BASICS: NATIONAL

"TO BE PAID [AS A] BENEFIT…, A DIAGNOSTIC TEST MUST BE ORDERED BY A PHYSICIAN WHO IS PART OF THE BENEFICIARY'S TREATING CARE TEAM, AND THE RESULTS MUST BE USED IN THE MANAGEMENT OF THE BENEFICIARY'S SPECIFIC MEDICAL PROBLEM."

National Coverage Determination (March 2018):

CMS covers FDA-approved NGS tests for patients with recurrent, relapsed, refractory, metastatic, or advanced stage (III or IV) cancer.

https://www.cms.gov/medicare-coveragedatabase/view/article.aspx?articleId=56853
Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N) (2018). Federal Registrar.

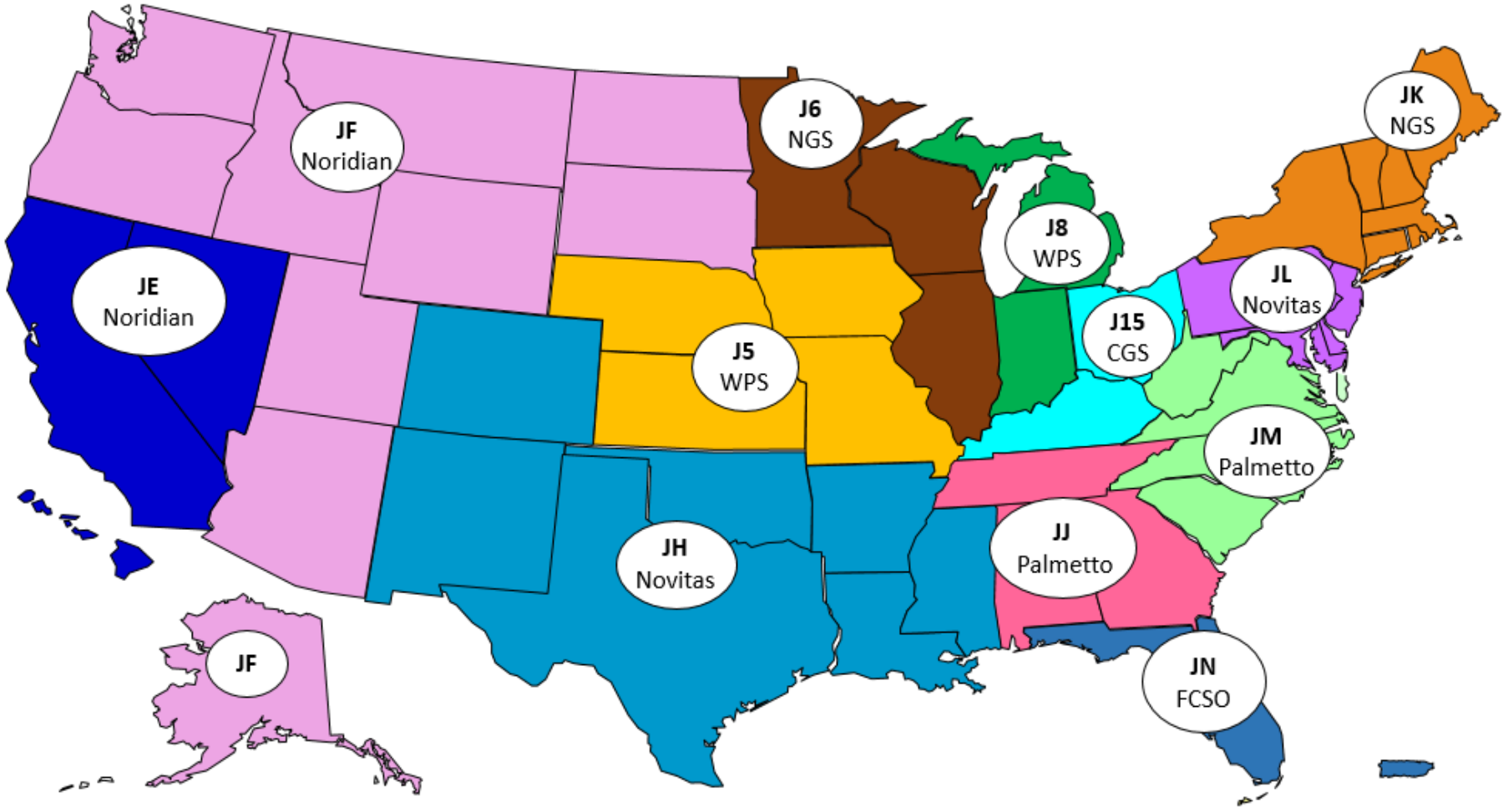
MEDICARE BASICS: REGIONAL

MACs (Medicare Administrative Contractors)

- Process claims
- Establishes local coverage determinations
  1. Does this count as a benefit?
  2. Is the test reasonable and necessary?
  3. Technical assessment of the tests
     - MolDX (Molecular Diagnostic Services) Program
       - Program that helps MACs determine whether the molecular tests reasonable and necessary for certain conditions
       - Lab-developed tests must submit technical data for review
       - Z codes identify the test itself with the MolDx and are required for claim submission

https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Who-are-the-MACs

A/B MAC Jurisdictions



https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Who-are-the-MACs

MEDICARE BASICS: 14-DAY RULE

- Outpatient 14-day Rule: *No longer an issue*
  - As of January 2018, changes to the Medicare Outpatient Prospective Payment System (OPPS), laboratories can now bill Medicare directly for biomarker testing within 14 days of their procedure/collection date.
  - Medicare Part B
- Inpatient 14-day Rule:
  - There remains issues with reimbursement for biomarker testing within 14 days of an inpatient stay
  - Medicare Part A
    - Reimbursement is by diagnosis-related groups (DRGs)

MEDICARE BASICS: 14-DAY RULE

- Inpatient 14-day Rule Cont:
  - Differences in structure between Parts A and B explain why the inpatient 14-day rule was not addressed simultaneously

Hospital Perspective: Not reimbursed for an expensive service

Medicare Perspective: Cost is incorporated into the DRG

PRIVATE INSURANCE

- Variable in their coverage and in their written policies
- Lab Benefit Managers (LBMs)
  - Help guide coverage decisions
    - Example: Blue Cross Blue Shield & Avalon

EXAMPLE: BLUE CROSS BLUE SHIELD & AVALON

Policy

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request

1. Using a validated test, molecular profiling to identify all of the established actionable driver mutations (*ALK*, *BRAF*, *EGFR*, *ERBB2(HER2)*, *KRAS*, *METex14* skipping, *NTRK 1/2/3*, *RET*, *ROS1)* is considered **MEDICALLY NECESSARY.**
2. Testing for *BRAF*, *EGFR*, and/or *MET* mutations before any systemic therapy initiation in patients with non-Small Cell Lung Cancer (NSCLC) is considered **MEDICALLY NECESSARY**.
3. Testing for *ALK*, *RET*, and/or *ROS1* rearrangements before any systemic therapy initiation in patients with NSCLC is considered **MEDICALLY NECESSARY.**
4. Testing for *NTRK1/2/3* gene fusions is considered **MEDICALLY NECESSARY** for individuals with NSCLC before first-line or subsequent targeted therapy
5. To direct therapy in patients with NSCLC, analysis of PD-L1 expression by immunohistochemistry is considered **MEDICALLY NECESSARY.**
6. *KRAS* molecular testing is considered **NOT MEDICALLY NECESSARY** as a routine stand-alone assay and as a sole determinant of targeted therapy.

https://www.southcarolinablues.com/web/public/brands/medicalpolicy/external/external-policies/testing-for-targeted-therapy-of-non-small-cell-lung-cancer/

EXAMPLE: BLUE CROSS BLUE SHIELD & AVALON

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of a patient's illness.

1. Analysis of PD-L1 expression by immunohistochemistry in all other situations is considered **NOT MEDICALLY NECESSARY**.
2. As a stand-alone assay and as a sole determinant of targeted therapy, analysis of a variants of uncertain significance (VUS), even if the VUS occurs in a gene in which other variants are clinically actionable, s considered **NOT MEDICALLY NECESSARY**.
3. To direct targeted therapy in patients with NSCLC, analysis for genetic alterations in genes not mentioned above is considered **NOT MEDICALLY NECESSARY.**

- They cite at least 12 individual studies and guidelines from NCCN, CAP-MAP-IASLC, ASCO, ESMO, and NICE in support rationale for what it deems medically necessary

https://www.southcarolinablues.com/web/public/brands/medicalpolicy/external/external-policies/testing-for-targeted-therapy-of-non-small-cell-lung-cancer/

EXAMPLE: BLUE CROSS BLUE SHIELD & AVALON

Policy

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request

1. For individuals diagnosed with non-small cell lung cancer (NSCLC), cell-free DNA/circulating tumor DNA (cfDNA/ctDNA) testing is considered **MEDICALLY NECESSARY** in **any** of the following situations:
    a. When tissue-based testing is infeasible (i.e., quantity not sufficient for tissue-based test or invasive biopsy is medically contraindicated)
    b. In the initial diagnostic settingwhen there is insufficient tissue to allow testing for broad molecular analysis following pathological confirmation of NSCLC (if an oncogenic driver is not identified, follow-up tissue-based analysis should be considered)
    c. In the initial diagnostic setting when tissue-based molecular analysis does not completely assess all recommended biomarkers due to tissue quantity or testing methodologies available. Recommended biomarkers include:
        i. *ALK* rearrangements.
        ii. *BRAF* mutations.
        iii. *EGFR* mutations.
        iv. *ERBB2* (*HER2*) mutations.
        v. *KRAS* mutations.
        vi. *MET*ex14 skipping mutations.
        vii. *NTRK1/2/3* fusions.
        viii. *RET* rearrangements.
        ix. *ROS1* rearrangements.
        x. PD-L1 expression levels.
    d. To aid in biomarker evaluation for treatment selection in the initial diagnostic setting (when the feasibility of timely tissue-based testing is uncertain).

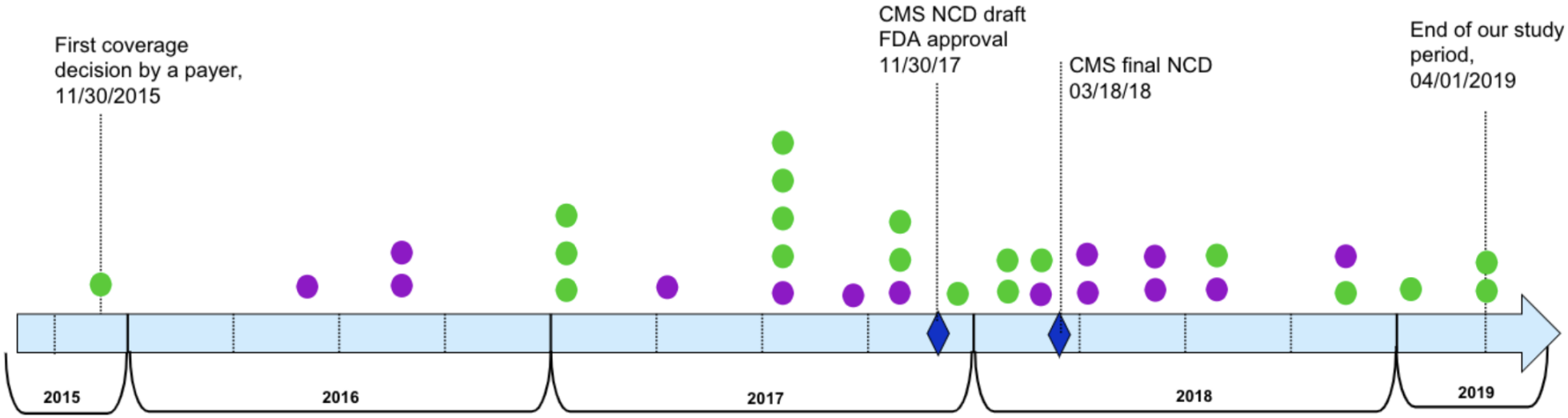
https://www.southcarolinablues.com/web/public/brands/medicalpolicy/external/external-policies/liquid-biopsy/

PRIVATE INSURANCE

- In a study of 92 private payers from until 2019, 75% had an explicit coverage policy

< 1 million enrollees
> 1 million enrollees

Figure 1. Timing of payer adoption of positive coverage for NGTS.



Trosman JR, et al. Value Health . 2020 May;23(5):551-558.

PRIVATE INSURANCE

- **Nearly half of the studies sample (55 million lives total) had a negative coverage policy**, with policy stating that sequencing was not covered for any indication or any sequencing test

Trosman JR, et al. Value Health . 2020 May;23(5):551-558.

SC MEDICAID

- Coverage varies by State
  - The following excerpt is from the SC DHHS manual

PHYSICIANS SERVICES PROVIDER MANUAL

SOUTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES

Referral Out-of-State (OOS)
Specimens must be referred to a South Carolina Medicaid-enrolled independent laboratory, pathologist or hospital. OOS referrals to non-enrolled providers are not compensable through the Medicaid program. Providers cannot bill Medicaid beneficiaries when Medicaid would have paid the lab service if appropriate billing and referral procedures had been followed.

Genetic Studies
Medicaid will reimburse for genetic studies if ordered by an attending physician and requested as a direct diagnosis and treatment tool. The genetic study may be ordered as a preventive measure; however, the prevention must have a direct correlation with the treatment of the patient and the patient's family, or serve as an inhibitor to institutionalization. Medicaid will not reimburse for genetic research.

No specific mention of biomarker testing for any precision medicine therapies

https://provider.scdhhs.gov/internet/pdf/manuals/Physicians/Manual.pdf

SC MEDICAID

- Coverage varies by State
  - Administered predominantly by managed care organizations (e.g., Select Heath)

AmeriHealth Caritas
Care is the heart of our work

Molecular analysis for targeted therapy of non-small cell lung cancer

Clinical Policy ID: CCP.1218

Recent review date: 7/2022

Next review date: 11/2023

Select Health of South Carolina

Circulating tumor DNA and circulating tumor cells for cancer management (liquid biopsy)

Clinical Policy ID: CCP.1516

Recent review date: 7/2022

Next review date: 11/2023

Policy contains: Cancer, circulating tumor cells, circulating tumor DNA, liquid biopsy

https://www.selecthealthofsc.com/pdf/provider/policies-20230208/ccp1218-molecular-analysis-targeted-therapy-non-small-cell-lung-cancer.pdf
https://www.selecthealthofsc.com/pdf/provider/policies-20230208/ccp1516-circulating_-tumor-dna-circulating-tumor-cells-cancer-management-liquid-biopsy.pff

SC MEDICAID: END OF CONTINUOUS ENROLLMENT

- **Expected transitions and loss of coverage for vulnerable populations in 2023**
- At the start of the COVID-19 pandemic, Congress passed legislation for Medicaid to keep people continuously enrolled through the end of the COVID-19 public health emergency.
  - Rather than an annual renewal process
- Congress signed the 2023 Consolidated Appropriations Act in December 2022 ending continuous enrollment on March 31, 2023
- Redetermination anticipated across the April-June 2023 timeframe for SC

https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-the-unwinding-of-the-medicaid-continuous-enrollment-provision/#:~:text=As%20part%20of%20the%20Consolidated,matching%20funds%20through%20December%202023.

Didactic Q & A

Case Presentation: Prior Authorization Requirements for Biomarkers

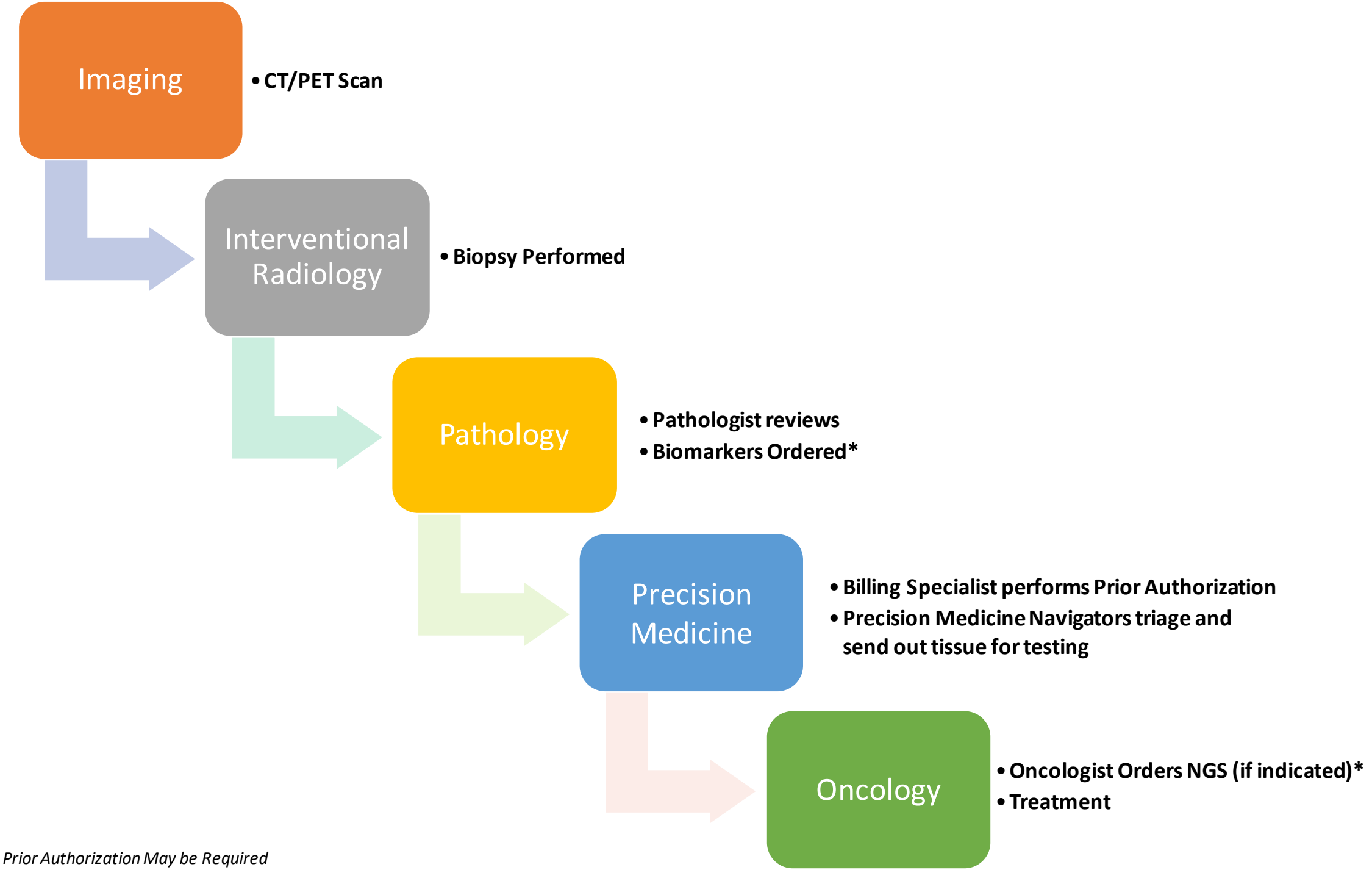
Amanda Hanson, MS, CGMBS, MB (ASCP)CM

Director, Precision Medicine

Spartanburg Regional Healthcare System

Current workflow description

- The patient is referred for imaging.
- If a pulmonary nodule is detected, the patient will undergo a biopsy in interventional radiology and the sample will be sent to pathology.
- Upon case review, the pathologist will order necessary biomarkers and reflex all primary or metastatic non-small cell lung cancer adenocarcinomas for lung panel testing (EGFR, ROS1, BRAF and ALK).
- At that time the Billing Specialist will receive a copy of the order and if required, perform the necessary prior authorization.
- Once complete, the Billing Specialist documents the PA number in the EMR and will notify the Precision Medicine Navigators so that can proceed to triage and send out the case.



**Indicates where Prior Authorization May be Required*

Primary Challenges/Barriers

- The two primary challenges:
- Justifying the allocation of full-time employees to a non-revenue generating role required to navigate evolving billing practices and prior authorization requirements
- Lung core biopsies yield limited tissue, necessitating efficient triaging of the case to provide the patient with the best opportunity for testing results that yield treatment options

Aim and vision

- **What are we trying to improve?**
- The objective of our process is to enhance the turnaround time for relevant biomarker results, mitigate the financial burden on patients, and ensure timely delivery of appropriate treatment to the right patient.

- **Vision**
- When functioning optimally, this system is designed to prevent patients from receiving unexpected laboratory bills.

Changes to the workflow & Impact

- Previously, the assigned Pathologist had to delay sending tissue samples for biomarker testing until an Oncologist was assigned to sign the order.
- This caused delays in obtaining results and some patients failed to follow up with their Oncologist.

Workflow change:

- a new process was implemented three months ago; if lung panel reflex order is needed, the IR Doctor will place the order

Results:

- Ensures lung panel results are available during the patient's initial oncology visit
- Encourages patients with actionable variants to follow up with their Oncologists for treatment options

Case Presentation Discussion

Specific Questions to the Group	
Q1	
Q2	
Q3	

Wrap-Up & Post-Session Poll Questions

A Few Reminders:

Next ECHO Session: 5/26/23 8:00 a.m.

Next Didactic Presenter: TBD

Materials and Resources will be made available soon.
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
(https://forms.office.com/r/TNR4UT0uc1)

Questions: Contact korey.hofmann@cancer.org and kim.hale@cancer.org

American Cancer Society

Project ECHO

THANK YOU