February 26, 2025 | *Washington D.C.*

LUNGevity Precision Medicine Summit
Meeting Summary

Executive Summary: Enhancing Access to Biomarker Testing for NSCLC

The LUNGevity Lung Cancer Precision Medicine Summit, held on February 26, 2025, focused on strategies to improve biomarker testing for non-small cell lung cancer (NSCLC). Key discussions highlighted challenges related to regulatory inconsistencies, reimbursement issues, patient-provider communication, and the importance of decision-making processes in advancing precision medicine (PM) in hospitals. Participants emphasized the need for coordinated institutional alignment, payer engagement, and robust data generation to streamline biomarker testing workflows and ensure broader adoption of precision medicine. Addressing these challenges will ultimately improve patient outcomes and access to timely, personalized care.

Regulatory and Reimbursement Challenges

A central challenge is the regulatory inconsistency within Medicare, especially regarding reflex testing—a practice where biomarker tests are ordered automatically upon diagnosis. Current Medicare policies lack clear guidance, leading to confusion about who can order tests and when. Medicare Administrative Contractors (MACs) interpret test-ordering rules differently, creating a patchwork of regulations. For example, while one MAC allows pathologists to order biomarker tests, another does not, despite both following the same underlying rule. These discrepancies result in delays and unnecessary barriers for patients.

Additionally, Medicare's fragmented reimbursement structure complicates the reimbursement process for next-generation sequencing (NGS) tests in NSCLC, with issues like the 14-day rule, which limits how labs can bill for biomarker tests. This creates confusion for providers and administrators, exacerbating delays. Clarifying these policies, eliminating delays in biomarker test ordering for inpatients, and aligning reimbursement for tests like liquid biopsies and comprehensive biomarker panels across all stages will help more sites implement 'reflexive' workflows, improving patient access.

Decision-Making Considerations for Advancing Precision Medicine in Hospitals

To advance PM within hospitals, it is essential to address institutional alignment, payer engagement, and data generation. Successful integration of PM requires collaboration across hospital departments, including administrators, oncologists, and laboratory technicians, to streamline biomarker testing workflows. Engaging private payers is also crucial for ensuring broader access to testing and supporting value-based reimbursement models. Additionally, compiling compelling data on the financial and clinical benefits of comprehensive testing and streamlined workflows is critical for influencing payers and guiding hospital decision-making processes.

The 4R Care Sequence Model: Improving Patient-Provider Communication

The 4R Care Sequence Model emerged as a key solution for improving patient-provider communication regarding biomarker testing. This model integrates biomarker testing into a patient's personalized care plan, helping patients understand how tests fit into their treatment timeline. By clearly outlining the purpose, timing, and role of testing, the model reduces patient anxiety, improves comprehension, and encourages more informed decision-making. It is particularly effective in addressing health literacy barriers and ensuring underserved populations have access to clear, actionable information about their care. Some sites also successfully use it to refashion and streamline biomarker testing workflows.

Conclusion and Next Steps

To improve access to biomarker testing for NSCLC, policy updates are needed to clarify Medicare's rules for reflex testing and streamline reimbursement across payers. Aligning reimbursement for comprehensive biomarker panels will ensure more timely and accurate testing. The 4R Care Sequence Model provides a valuable framework to enhance patient understanding and improve communication between healthcare providers and patients.

Advancing PM in hospitals requires aligning institutional workflows, engaging payers, and generating robust data to demonstrate the value of comprehensive biomarker testing. LUNGevity's working groups will focus on advocating for best practices in testing workflows and gathering the data needed to drive policy changes, ultimately ensuring more equitable access to precision medicine for all NSCLC patients.

Detailed Meeting Summary

The LUNGevity Lung Cancer Precision Medicine Summit, held on February 26, 2025 in Washington DC, convened a diverse group from the lung cancer community—including oncologists, pathologists, nurses, payers, health system administrators, patient advocates, and industry representatives—to discuss strategies for improving access to biomarker testing for NSCLC. Updates were provided from four working groups, each focused on advancing biomarker testing in NSCLC.

Working Group Updates

- Reflex Testing: Hospital Workflow Subgroup – Dr. Mary Beth Beasley (Mount Sinai), shared an update on the subgroup's research, which involves qualitative interviews at six institutions to identify best practices for ensuring timely biomarker testing and results availability. She also highlighted the proposed Reflex Testing Mentorship Program under the leadership of the Association of Cancer Care Centers (ACCC), in partnership with LUNGevity, which will translate these best practices into practical application.

- Reflex Testing: Policy & Reimbursement Subgroup – Nikki Martin (LUNGevity) and Dr. Bruce Quinn (Bruce Quinn Associates) discussed policy challenges impacting reflex biomarker testing. Nikki presented a survey framework, conducted in partnership with the Association for Molecular Pathology (AMP) and the American Society of Clinical Pathology (ASCP), which is gathering feedback from labs and healthcare providers. One initial theme reveals that sites not conducting standardized workflows cite Medicare's 14-day rule and lack of reimbursement for early-stage disease as major barriers.

  Bruce Quinn provided historical context on Medicare's inconsistent test-ordering policies, noting that while MolDX permits pathologists to order biomarker tests, Novitas—a different MAC—interprets the same 30-year-old rule differently. LUNGevity is collaborating with Bruce Quinn to build a coalition of hospitals in the MolDX region to share their experiences and demonstrate the impact of pathologist-initiated testing on patient care. These efforts will help determine whether to push for a consistent national policy.

- Value Proposition – Alison Urvalek (Eli Lilly) and Liam Lee (AstraZeneca) updated the group on efforts to develop a webpage, the **"Clinical Value of Biomarker Testing"**, featuring unified messaging and summaries of high-impact studies on the themes of

advancing patient care through biomarker testing; providing accessible and equitable biomarker testing; and operational improvements for testing. This resource will support hospital administrators, cancer line executives, and other decision-makers in advocating for healthcare system investments in comprehensive biomarker testing.

- Practice Guidelines – Dr. Christine Lovly (Vanderbilt Medical System), shared a video update on a collaborative effort among national guideline experts to develop a commentary synthesizing biomarker testing recommendations. This initiative aims to clarify guideline recommendations for providers and payers, supporting consistent test ordering by clinicians and coverage policies by insurers.

Participants returned to discussing the work groups' activities at the end of the day when they could consider how the insights from expert panels and participant discussion could be pulled through to refine and enhance their focus.

Expert Panels and Presentations

There were three panels/presentations at the Summit:

- Policy and Reimbursement Barriers to Reflex Biomarker Testing
- Decision-Making Processes in Precision Medicine
- Improving Patient-Provider Communication on Biomarker Testing

Panel on Policy and Reimbursement Barriers to Reflex Biomarker Testing

The first panel examined systemic policy and reimbursement challenges hindering the adoption of reflex biomarker testing in NSCLC. Panelists included Dr. Eric Konnick (University of Washington), Dr. Gabe Bien-Willner (MolDx), and Dr. Bruce Quinn.

***Key challenges include*:**

- Limited regulatory guidance on reflex testing
- Inconsistent reimbursement structures creating access disparities
- The 14-day rule causing confusion and delays
- Policy and guidelines lagging behind scientific advancements

Regulatory Ambiguity Limiting Reflex Testing Adoption

Hospitals could improve turnaround times and ensure appropriate testing by instituting reflex testing and allowing pathologists to order biomarker tests upon diagnosis. However, Medicare provides minimal guidance, offering only brief definitions of reflex testing and standing orders. Reflex testing is conditional—meaning it only happens when a specific trigger is met (e.g., a biomarker test after an NSCLC biopsy result). Standing orders are a broad preauthorization for tests on all patients in a category (e.g., all NSCLC cases get biomarker testing). Although Medicare recognizes both, although providing minimal guidance, the key regulatory issue is that pathologists cannot order tests unless specific conditions are met. Without clear medical necessity, orders risk compliance issues with payers like Medicare, making reflex testing more aligned with regulations while standing orders face greater scrutiny. Additionally, since Medicare does not recognize pathologists as treating physicians, uncertainty remains about when they can independently order tests, particularly broad molecular panels.

This lack of clarity hinders real-world clinical practice, where timely molecular insights are critical for treatment decisions. Greater specificity in Medicare regulations could standardize workflows and improve patient outcomes.

Inconsistent Reimbursement Structures Creating Access Disparities

Biomarker test reimbursement is fragmented, with tests covered under different fee schedules. For example, ER/PR/HER2 testing for breast cancer falls under the Physician Fee Schedule (PFS), while broad next-generation sequencing (NGS) panels are on the Clinical Lab Fee Schedule (CLFS), which panelists suggested could be viewed as requiring oncologist authorization.

This discrepancy allows breast cancer biomarkers to be routinely ordered, while NSCLC tests face administrative hurdles. Additionally, panelists discussed the eventual development of biomarker-specific ICD-10 codes to integrate molecular panels automatically based on NSCLC diagnosis. While there would be many challenges for this approach to account for multiple biomarker signatures and tissue-agnostic markers, if implemented, it could push payers to update coverage policies.

The 14-Day Rule Causing Confusion and Delays

Originally intended to prevent duplicate billing, the 14-day rule restricts how labs bill Medicare

for molecular tests. A 2017 exemption allows direct billing for DNA/RNA-based tests after an outpatient procedure, but inpatients remain subject to the rule. To avoid billing under the Diagnosis-Related Group (DRG) payment, hospitals may delay testing until after discharge.

The panel discussed confusion regarding the rule's applicability to inpatients. While the discussion incorrectly relayed that the rule no longer applies to inpatients, LUNGevity has fact-checked this with multiple experts and confirmed that it still does.

Additional issues include:

- Private payers inconsistently applying CMS guidance
- Hospitals mistakenly applying the 14-day rule to outpatient samples

The Need for Policy Evolution in Precision Medicine

Panelists emphasized the need for continued advocacy for regulatory updates and aligning payer policies with clinical best practices. In particular, they discussed how biomarker testing should be an essential part of the NSCLC diagnosis, with molecular characteristics like HER2 positivity becoming a defining feature of the disease. By framing the omission of biomarker testing as malpractice, this approach could leverage legal and policy frameworks to ensure universal testing, prompting payers and providers to align with these standards. Faster updates to guidelines, such as those from NCCN, and a more cohesive reimbursement framework would enable timely biomarker testing, ensuring patients receive the right treatment without unnecessary delays.

Panel on Decision-Making Processes in Precision Medicine

This panel featured Dr. Karen Kelly (International Association for the Study of Lung Cancer - IASLC), Dr. Mark Socinski (Advent Health System), Jennifer Aversano, RN (Northwest Community Hospital), and Dr. Eric Konnick. Improving access to biomarker testing and precision medicine requires a coordinated approach that engages payers, aligns institutional stakeholders, educates providers, and generates evidence supporting comprehensive testing. The challenges are multifaceted, spanning workflow barriers, financial considerations, and policy limitations. Addressing these issues requires both top-down policy changes—such as quality measures tied to reimbursement—and bottom-up efforts, including collaboration between payers, providers, and institutions. Ultimately, the goal is to ensure that patients receive the right treatment at the right time, minimizing harm and improving outcomes.

Key areas that require attention include:

- Institutional alignment to streamline biomarker testing workflows
- Payer engagement and data generation

Institutional Alignment to Streamline Biomarker Testing Workflows

Expediting biomarker test results in time for a patient's first clinic visit is critical but often hindered by process inefficiencies, payer barriers, and lack of coordination. Cancer service line executives and hospital administrators need clear frameworks for integrating precision medicine. Some institutions have improved efficiency by implementing pathology-driven reflex testing workflows, ensuring oncologists focus on interpreting results rather than coordinating test orders. Expanding these best practices to community settings remains a challenge.

Bringing together key parties—administrators, nurses, lab technicians, pathologists, oncologists, and patients—is necessary to identify gaps and refine processes. Ongoing education is also crucial for both physicians and patients to fully understand test results and their implications.

Payer Engagement and Data Generation to Support Broader Adoption of Precision Medicine

Equitable access to biomarker testing depends on effective collaboration between payers and healthcare institutions. While much of the policy discussion has focused on CMS regulations, private payers also play a crucial role in determining test accessibility and coverage. Engaging payers and educating hospital administrators about the clinical and financial value of biomarker testing is essential for fostering alignment and improving patient outcomes. Direct payer engagement has shown to lead to better coverage policies and more consistent testing.

To further drive institutional adoption, financial and reputational incentives tied to quality measures can help integrate best practices into diagnostic workflows. Aligning workflows—such as pharmacy coordination and rapid treatment protocols—with payer expectations can also support better reimbursement and more consistent test implementation.

At the same time, a compelling evidence base is needed to demonstrate the importance of comprehensive biomarker testing. Generating and communicating data on the financial and clinical impacts, including patient harm, of incomplete or delayed testing is critical for influencing payer policies and guiding decision-making in hospitals. Additionally, improving coordination in community pathology—particularly around tissue sample preservation and educating institutions on emerging best practices—can help standardize testing practices across the healthcare system.

By improving institutional workflows, fostering payer collaboration, and strengthening data generation, biomarker testing can be more effectively integrated into oncology care—ensuring timely and appropriate treatment for patients.

The 4R Care Sequence Model: Improving Patient-Provider Communication on Biomarker Testing

This panel featured Julia Trosman, PhD (Center for Business Models in Healthcare) and Dr. Frank Weinberg (University of Illinois, Chicago) discussing the 4R Care Sequence Model, a tool designed to enhance patient-provider communication and streamline biomarker testing workflows, particularly for underserved populations.

Key aspects of the 4R Care Sequence Model include:

- Personalized care plans that map biomarker testing within the full treatment timeline
- A provider workflow tool ensuring key steps in biomarker testing are followed
- A patient communication aid clarifying the purpose, timing, and role of biomarker testing

Enhancing Patient Understanding and Reducing Anxiety

A core benefit of the 4R Care Sequence Model is that it visually integrates biomarker testing into a patient's overall care plan. Rather than vague instructions such as "Your doctor will discuss results next week," the tool provides a structured roadmap, setting clear expectations and reducing anxiety.

Key outcomes from implementation at multiple cancer centers:

- Improved patient comprehension of biomarker testing and impact on treatment selection

- Increased patient willingness to wait for results
- Empowered patients who feel more in control of their care, leading to lower levels of stress and uncertainty.
- Clinician usability in guiding discussions and ensuring key results were explained before treatment proceeded.

Implementing the 4R Model: Flexibility and Institutional Adoption

The 4R Model is available for free to institutions, but successful adoption requires an implementation strategy tailored to each institution's needs. The model remains actively updated to align with evolving guidelines, such as NCCN NSCLC guidelines.

Institutions can integrate the model at different levels:

- Larger cancer centers: May use the model to optimize workflows, such as reducing wait times for imaging or streamlining test result communication.
- Smaller institutions: Can implement the framework with approximate timelines if their biomarker testing processes are already efficient.

Institutions interested in using the 4R Care Sequence Model can access it via the **ACCC provider page** or through **the model's website**.

Addressing Provider Discomfort in Communicating About Biomarker Testing, Particularly in Lower-Income Populations

The 4R model proves particularly effective in helping providers communicate complex biomarker results, a task that can be challenging due to the multifaceted nature of biomarkers compared to imaging. Biomarkers often require multiple interpretations, making them harder to explain to patients.

Dr. Weinberg, during his time at the VA, utilized written explanations to reduce patient anxiety and enhance understanding, particularly for newly diagnosed patients. The 4R model aligns with this approach and is particularly valuable when educating lower-income populations. Dr. Weinberg emphasizes that patients with lower health literacy can understand biomarker concepts when these concepts are explained clearly, challenging the misconception that they are too complex for these groups. The 4R model helps support providers in achieving this clarity.

Big Picture Trends in Precision Medicine and Next Steps for LUNGevity

The final session of the Summit synthesized insights from the day's discussions—including updates from the four workgroups, panels on policy and reimbursement, decision-making processes, and patient-provider communication models—to identify overarching trends in precision medicine. Participants then explored how these trends should shape LUNGevity's precision medicine efforts, ensuring that the workgroups remain aligned with emerging challenges and opportunities.

The emerging trends include:

- AI and Digital Innovation: AI is transforming biomarker-driven care, enhancing imaging, pathology, and clinical decision-making, though infrastructure challenges remain for its widespread adoption in digital pathology.

- Advancements in Biomarker Testing: The shift toward broad biomarker panels, integrating multi-omics and immunology, promises better tumor profiling but faces challenges like workflow integration, staffing shortages, reimbursement, and the need for specialized lab capabilities.

- Targeted Therapies: New drug targets and antibody-drug conjugates (ADCs) are expanding treatment options, but their success depends on updating diagnostic frameworks to identify biomarkers appropriately.

- Policy and Reimbursement: Evolving value-based contracts and efforts to adapt ICD-10 codes for biomarker diagnostics are crucial for improving access, though significant coordination with international bodies like the WHO and CDC will be needed for implementation.

- Quality and Legal Considerations: As precision medicine expands, there is increasing need for standardized quality measures. Non-adherence to testing guidelines raises legal risks, emphasizing the importance of oncologists staying informed on current and emerging standards.

These trends will guide LUNGevity's working groups as they refine their focus and strategies to address the evolving landscape of precision medicine.

Aligning LUNGevity's Working Groups with Panel Insights and Precision Medicine Trends

In light of these insights and other expert perspectives, LUNGevity's working groups will continue focusing on current activities while aligning their efforts with these emerging trends, ensuring they are positioned to address both the challenges and opportunities identified during the Summit. The following outlines next steps for each group with a graphical summary below:

Value Proposition Working Group

- Clinical Value of Biomarker Testing Webpage Expansion: Expand valuable content and visibility of the webpage, and explore partnerships with like-minded organizations to increase its reach (current activity).

- Evidence Development on Comprehensive Testing: Payers and decision-makers require more research on the harms of incomplete biomarker testing and delays in receiving results. Stronger evidence must be compiled from existing literature to support the coverage of comprehensive panels.

Guidelines Working Group

- NSCLC Biomarker Testing Guidelines: Efforts will continue to publish and promote a biomarker testing guidelines statement distilling recommendations (current activity).

- Guidelines and Provider Perspective: Additional data is needed to understand whether NSCLC guidelines serve as a barrier to biomarker test orders, and a survey of community doctors particularly in rural, small practices could help assess how guidelines impact test ordering practices.

Reflex Testing Hospital Workflow Sub Group

- Reflex Testing Workflow Study: Finalize the best practices in timely biomarker testing workflows study and launch the ACCC Reflex Testing Mentorship and QI Initiative (current activity). Explore how to incorporate the 4R model and address Quality Not Sufficient (QNS) issues that hinder testing success at certain sites.

- Medical Society Endorsement: The group will discuss whether it should identify a medical society that can endorse biomarker testing for all stages of NSCLC and/or reflex testing.

Reflex Testing Policy & Reimbursement Sub Group

- Publish lab/HCP policy barrier to biomarker testing survey results and pursue broad collaborative work to use results in communication with CMS (current activity).

- Build coalition of sites supportive of pathologist-initiated biomarker testing to communicate about experience (could support ACCC Reflex Testing Mentorship Initiative).

- 14-Day Rule Clarity & Education: The 14-day rule remains confusing for hospitals. To address this, a one-pager explaining the rule and a myth-busting paper/webinar will be explored in partnership with hospital associations and professional societies.

- NCD & Staging-Based Denials: The group will discuss how the National Coverage Determination (NCD) is acting as a barrier to biomarker testing for early-stage NSCLC due to staging-related claim denials.

- ICD-10 Code Updates: An investigation into updating ICD-10 codes for biomarker-specific diagnostics will be undertaken, ensuring alignment with evolving guidelines.

- Liquid Biopsy Reimbursement & Cancer Staging in Claims: The group will discuss the lack of staging information in claims, which contributes to a 30% denial rate for liquid biopsies, and consider its role in working toward clearer reimbursement policies.

Joint Working Group Activities

- Reflex Testing Hospital Workflow & Value Proposition Sub Groups: The groups will discuss developing tools for cancer line executives/administrators, such as a paper on the clinical and/or economic benefits of reflex testing and/or a business case template for presenting biomarker testing proposals to leadership.

- All Work Groups: LUNGevity will seek to connect the working groups with ASCO leadership developing the NSCLC Biomarker Testing Quality Measure and consider endorsing the measure, if appropriate.

LUNGevity Working Groups – Areas of Focus 2025-26

Value Proposition Working Group	• Enhancing the visibility of the Clinical Value of Biomarker Testing web page • Assemble evidence on harms of incomplete biomarker testing
Guidelines Working Group	• Distilling NSCLC biomarker testing guidelines for providers and payers • Evaluating the impact of guidelines on test utilization and coverage in diverse practice settings
Reflex Testing Hospital Workflow Sub Group	• Continuing the qualitative best practices study across diverse sites and partnering on ACCC Reflex Testing Mentorship Initiative • Exploring 4R model integration to support reflex testing adoption
Reflex Testing Policy & Reimbursement Sub Group	• Leveraging survey findings on policy barriers for future CMS discussions • Forming a coalition of successful pathologist-led testing sites. • Creating myth-busting resources on the 14-day rule • Exploring potential for biomarker-specific ICD-10 codes
Joint Working Group Initiatives	• Evaluating how to synthesize and leverage existing clinical and economic evidence to strengthen cancer executives' ability to make the case for timely comprehensive biomarker testing.

Final Reflections and Next Steps

The Summit highlighted the critical need for cross-sector collaboration to overcome the challenges facing precision medicine. Experts and working group leaders emphasized the importance of addressing key issues such as regulatory guidelines, reimbursement, optimization of workflow practices, while ensuring equitable access to advancements in AI, more advanced biomarker testing, and new types of targeted therapies.

As LUNGevity moves forward, its working groups will incorporate these insights into their strategies, ensuring they stay aligned with the evolving landscape of precision medicine. Continued collaboration will be essential in driving meaningful, lasting change across the field.

LUNGevity extends its gratitude to the broader lung cancer community for its ongoing support and partnership in identifying solutions that ensure all patients receive comprehensive biomarker testing at diagnosis, enabling timely, biomarker-driven care for the best possible outcomes.