



ASSOCIATION
FOR MOLECULAR
PATHOLOGY



2022 Molecular Pathology Economics Summit

Summary of Themes

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Introduction

Molecular diagnostics is a rapidly evolving field with frequently changing standards for care that challenge the current paradigm for coding, coverage, and payment. In 2019, the Association for Molecular Pathology (AMP) brought together stakeholders from across the molecular diagnostics spectrum for a one-day summit aimed at improving the molecular diagnostics economic landscape. Following the success of this event, the COVID-19 pandemic and its call to action for molecular professionals across the globe exacerbated the concerning trends discussed at the first Summit and introduced new issues that the field needed to overcome.

On July 15, 2022, AMP reconvened stakeholders from across the molecular diagnostics spectrum to harness to collective expertise of our community to advance the national dialogue toward improving patient access to appropriate molecular diagnostic care. The 2022 Molecular Pathology Economics Summit (the Summit), included 67 attendees representing the molecular professionals, clinical laboratories, diagnostics industry, pharmaceutical companies, trade and professional associations, and patient advocacy groups. Through a guided discussion, attendees discussed key issues impacting the field, such as the COVID-19 pandemic, coding, pricing, and reimbursement as well as potential solutions. Additionally, AMP debuted a novel “Innovation Lab” exercise, where stakeholders presented case examples of work their organization was already undertaking to address barriers to appropriate molecular diagnostic care. Following the presentations, the participants discussed collective actions the field could take to keep pushing these successes forward.

The objectives of the 2022 Summit were as follows:

- Analyze the short- and long-term economic impacts of the COVID-19 pandemic to the molecular diagnostic field and patient access.
- Identify the aspects of coding, pricing, and reimbursement that create barriers to appropriate patient access.
- Discuss potential solutions to identified barriers and prioritize discrete action items that the various stakeholder groups can focus on before the 2023 AMP Molecular Pathology Economics Summit on September 12, 2023¹.

Summarized below are the barriers identified and potential solutions discussed during the morning sessions of the 2022 Summit. AMP will continue to advance conversations toward improving patient access to appropriate molecular diagnostic testing and intends to actively update Summit attendees on progress towards these goals at the 2023 Summit.

¹ <https://www.amp.org/advocacy/amp-molecular-pathology-economics-summit/>

Facilitated Discussion Sessions: Key Themes and Solutions

The impact of the COVID-19 pandemic on molecular diagnostic tests, laboratories, and patient access

The global challenges created by the COVID-19 pandemic led to significant uncertainty for many clinical laboratories and diagnostics manufacturers who had to make time sensitive business decisions on how much to invest in the development of diagnostics for COVID-19, how to navigate supply chain issues, maintain an adequate workforce, and more, all while not knowing if they would be sufficiently reimbursed for their efforts². In fact, one attendee shared that they are still experiencing issues with reimbursement for COVID-19 diagnostic tests two years later.

As it became certain that the pandemic would not resolve quickly, the unprecedented demand on testing capacity continued to face numerous hinderances. Participants relayed how many clinical laboratories and diagnostic manufacturers struggled with navigating the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) process, and scarcity of supplies (e.g., plastics, personal protective equipment, and collection devices). To scale up COVID-19 diagnostic testing, clinical laboratories needed to quickly shift their focus to SARS-CoV-2 testing and personnel were transferred from other sectors of the laboratory. Additionally, laboratories had to adapt and respond to many restrictions that were placed on their staffing practices to prevent the spread of COVID-19 within their institutions. As in other sectors of the economy, the molecular pathology field also experienced a large workforce shift as a substantial portion of pathologists and laboratory technologists left the field or were recruited to new testing laboratories that were being created. Summit attendees noted that laboratories are still struggling to retain technologists with the workforce dwindling, possibly due to COVID-19 burnout, as seen in other healthcare settings.

As was widely reported, patient care in many circumstances was severely impacted by COVID-19. Elective surgeries were canceled or delayed due to the need to care for patients with COVID-19 and efforts to reduce exposure within the healthcare setting. At times, patients could not even visit their doctors in person due to government ordered shutdowns and other advisories intended to protect staff and reduce spread of SARS-CoV-2 the public. Due to these circumstances, patients had to delay routine screenings. Telehealth helped mitigate some of these issues but while it could supplement some medical care, it could not fully replace it. Tragically, many summit attendees reported that they are now seeing cancers diagnosed at later stages creating more urgent health issues due to the consequences of delayed care.

Barriers to patient access through coding, pricing, and reimbursement

Coding

The most agreed upon reimbursement barrier is the complexity of the coding system. There are multiple types of codes that exist within the coding system and the most commonly used coding system is the American Medical Association (AMA) Current Procedural Terminology (CPT®) code set, which includes

² <https://www.amp.org/advocacy/economics-of-testing-during-a-public-health-emergency-lessons-learned-from-two-years-of-covid-19/>

Category I codes. While it is the most commonly used, attendees noted the CPT® Category I code set struggles to keep up with the constantly evolving molecular diagnostics sector. The CPT® Editorial Panel is dependent on volunteers, and the process of obtaining a new code is very slow (normally 9-18 months).

Furthermore, attendees highlighted that while the CPT® coding system is the most used, there are other code sets that are used and add complexity to the system. It was also mentioned that a clinical laboratory or manufacturer could choose to obtain a CPT® Proprietary Laboratory Analyses (PLA) code to sidestep the problems with the Genomic Sequencing Procedure (GSP) CPT® codes; however, PLA codes come with their own issues. While a PLA code is easy to obtain, there are problems with coverage of the PLA codes by Medicaid, as each state has its own requirements. Lastly, attendees discussed the additional layer of coding complexity that is introduced when payers require that a unique test identifier in addition to a CPT® code be used for their claims, such as the Diagnostics Exchange™ (DEX) Z code system which is leveraged by the Palmetto Molecular Diagnostic (MoIDX) Program.

Finally, beyond the confusion on the appropriate use of codes, attendees expressed concern about how the complexities and availability of multiple coding systems and different payers' requirements negatively impact patient access to medically necessary tests. At times, it is difficult for laboratory professionals to know which codes to bill for tests properly and institutions often need to hire a coding expert to assist them. Attendees noted that confusion over coding could lead to physicians not offering patients testing either because they assume that the test will not be covered or that the cost would be passed on to the patient. For example, coverage and payment could be denied for two tests performed on the same patient due to similarities in the code descriptors even though the tests have distinct CPT® codes. The Centers for Medicare and Medicaid (CMS) National Correct Coding Initiative (NCCI) Edits were intended to eliminate redundancy when procedures were coded, such as an unlikely double transplant. However, attendees noted that while NCCI was intended to eliminate redundancy, the language it uses often conflicts with the AMA CPT® coding guidelines, thus creating additional confusion.

Pricing

During the pricing session, attendees spent a large amount of time discussing the Protecting Access to Medicare Act (PAMA). Congress enacted PAMA with the intention of creating a market-based pricing system for tests with the goal of ensuring accurate and appropriate pricing for molecular tests. During the first round of data collection directed by PAMA, confusion about requirements and its implementation resulted in seriously flawed data. Consequently, PAMA led to steep cuts to pricing such that reimbursement no longer reflects the effort or expertise required to perform the procedure. This could disproportionately impact smaller laboratories unable to handle this percentage of cuts. Additionally, there is no flexibility in the implementation of PAMA's statutorily mandated cuts, therefore such factors as increasing operational costs due to inflation or salary increases are not considered. Finally, there is concern that new codes will be crosswalked to existing codes subject to drastic cuts, resulting in cuts in the price for the new test even though its pricing data was not included in the PAMA data collection. As PAMA decreases the prices of new tests, reimbursement is not necessarily adequate to support the cost of performing the test, let alone research and development, provider training and education, and more. Furthermore, the effects of PAMA go beyond Medicare, as many commercial payer contractors base their prices on those set by Medicare, leading to a downward spiral of pricing over time.

Reimbursement/Coverage

AMP devotes a significant amount of time and resources responding to coverage policies, as limited or noncoverage policies are a major barrier to patient access to molecular diagnostic testing. Multiple patient advocacy stakeholders shared anecdotal evidence of patients unable to receive appropriate testing due to their insurance denials. The attendees agreed that when a patient must wait and see if the payer will reimburse their test that the patient is less likely to return to clinic, meaning the field should prioritize robust coverage policies. Somatic and germline molecular testing is the standard of care for many cancers, yet insurance coverage has not kept pace with biomarker testing. For example, some payers question the clinical utility of panel tests and state that every single gene included in a large panel must have clinical utility for the disease in question for the panel to be covered, otherwise it will be considered “investigational” or experimental and non-covered. Many of these issues stem from the lack of subject matter expertise among payers. One participant expressed concern that these issues also have a very large impact on the pediatric field.

The attendees noted that payers frequently do not have the in-depth knowledge of current guidelines or understand that these molecular tests are no longer supplementary but are required for providing the standard of care for patients. Attendees also acknowledged that this education gap has led to the proliferation of laboratory benefit managers (LBMs) helping payers develop coverage policies, and that stakeholders should determine how to engage more proactively with these groups. The attendees agreed that payers would benefit from education on performing these tests early in disease progression. Performing tests early in disease progression results in reduced costs over time, as severe illness is prevented, diseases are diagnosed earlier when they are most treatable, and emergency room visits are avoided, along with other quality metrics.

Proposed Solutions

Advocacy Regarding PAMA Reform

Representatives from AMP expressed concerns around “high cost test” language that has appeared in various pieces of legislation over the last few years and shared that the organization is doing an educational campaign for Congressional offices on the true value of molecular diagnostic testing. Furthermore, AMP is in the process of conducting a survey to investigate the real-world impact of PAMA on clinical laboratories and their decision making. Many other groups are also engaging in advocacy campaigns around the issues of reimbursement and long-term fixes to PAMA. The American Society for Clinical Pathology (ASCP) will conduct grassroots advocacy to educate congressional staffers on the importance of adequate reimbursement for laboratories. The American Clinical Laboratory Association (ACLA) is also developing educational materials on the value of laboratory testing. Furthermore, there are multiple groups assessing how PAMA will impact health equity. The stakeholders expressed interest in aligning around an advocacy strategy to address the issues with PAMA going forward. A representative from ACLA raised the *Saving Access to Laboratory Services Act (SALSA)* (S. 4449/H.R. 8188) as a potential pathway to reform PAMA. The SALSA legislation was introduced to Congress in July 2022 to address the flawed data collection process that PAMA used during its first iteration of implementation. It would establish a statistically valid sampling methodology to develop more accurate

fee determinations. Since the conclusion of the 2022 Summit, AMP along with 25 laboratory stakeholders signed onto a letter³ supporting the bill.

Broaden educational offerings and increase clinical decision-making support tools

Expanded education for physicians, patients, and hospitals on the role and importance of molecular diagnostic testing is crucial. Testing decisions must continue to be determined based on the most appropriate option for the patient and not based on what the ordering provider believes will be allowed by the patient's insurance coverage, as one attendee reported. A national infrastructure should be designed to better train providers on the role of molecular diagnostic tests and provide them with the tools to order the right tests to achieve the best outcomes for patients. Furthermore, education needs to be extended to payers to help them understand how to develop coverage policies for appropriate molecular diagnostic tests that will evolve as necessary with new evidence. Finally, the attendees stressed the need for payer education centering on the necessity to cover molecular tests early on in disease progression to improve patient outcomes. AMP is already working on payer education in this space and will be engaging the Economic Affairs Committee and other stakeholders from the Summit on how best to prioritize this work.

Streamline the coding system

The attendees agreed that a simplified coding system would make payment and coverage more consistent and relieve the administrative burden on laboratories. Attendees noted that an ideal coding system would include granularity for payers to see for what tests they are paying, an ability to be reimbursed for the interpretation and communication of molecular testing results, and adequate payment rates for the individual testing codes that reflect the true expenses of performing the test. While many stakeholders suggested characteristics that would make the current coding system more user-friendly and more adequately capture the work being performed, the group was unable to reach conclusion on specific steps forward. In the end, the attendees agreed that CPT® codes may be the best choice for laboratories to use as it is the most common and comprehensive, but the timeline for developing new codes is detrimentally slow. However, the COVID-19 pandemic showed that the process can be expedited, as AMA issued CPT® codes and CMS set payment rates within a matter of weeks, showing potential flexibilities in the system that can be considered. Additionally, the stakeholders will collectively look toward potential advocacy strategies to ensure that NCCI edits accurately reflect real-world ordering patterns. It became clear that alterations to the coding system will be a top priority in the future and AMP looks forward to continuing these conversations as the next Molecular Pathology Economics Summit.

Increased communication between pathologists, clinical care providers, and patients

One concern raised during the Summit was the barriers to communication between molecular pathologists, the clinical health team, and patients. A multidisciplinary clinical care team, one that includes a molecular professional, would be ideal. This multidisciplinary clinical care team can work to improve test ordering decisions, data harmonization, and better incorporation of molecular testing results into the patient's care plan. For example, a team consisting of an oncologist, molecular

³https://amp.org/AMP/assets/File/advocacy/2022_Sep_8_CLC_Provider%20SALSA_HR8188_%20S4449_Support_Letter_Final.pdf?pass=98

pathologist, and bio-informaticist would allow for a steady flow of information and proper ordering of tests. Unfortunately, all health care sites are resourced and structured differently, and this is not always feasible. The possibility was raised of harnessing and leveraging telemedicine to facilitate a team connecting online to attend to cases in hospitals without a multidisciplinary care team on-site, such as rural hospitals. This would not only increase patient access to molecular diagnostic tests but improve patient care as well. The response to the COVID-19 pandemic demonstrated the pivotal role that telemedicine can play in the health care system. Now is the time to figure out how this concept can be further applied to patient treatment to improve health outcomes.

Innovation Labs

During the afternoon session of the 2022 Summit, AMP premiered the inaugural Innovation Lab. Four organizations, the Cancer Support Community, Loxo@Lilly, Facing Our Risk of Cancer Empowered (FORCE), and Illumina, each presented their own solution to a current economic policy issue present in the field of molecular diagnostics and targeted treatments. Each group also suggested multiple potential action items the stakeholders could collaborate on to push their actions forward. The Summit attendees then participated in an open dialogue with the presenters to compare and contrast potential courses of action. Following the dialogue, the attendees selected action items to collaborate on over the next year.

An overview of each presentation as developed by the presenting organization, along with the agreed upon action items, can be found below:

Cancer Support Community

Cancer Support Community (CSC) focused on their grassroots efforts to implement policies for coverage of biomarker testing, to help better ensure patient access to testing, and education around testing. These goals are structured around three different initiatives: working with the American Cancer Society Cancer Action Network (ACS-CAN) led State Coalition on state legislation for Medicaid coverage of biomarker testing, finalizing a Biomarker Testing Coverage Landscape Analysis which highlights areas of improvement for payer coverage policy in non-small cell lung cancer, colorectal cancer, breast, prostate, ovarian, and pancreatic cancer, and creating a Grassroots Toolkit using results of the Landscape Analysis and their Plain Language Precision Medicine Lexicon to help enable the patients, caregivers, families and staff of CSC and CSC's network partners, including Gilda's Clubs, to better understand the issues and join in advocacy efforts on the state and federal level.

Potential Action Item for Stakeholders:

After conversation amongst attendees and CSC, it was decided the best route of action would be for the stakeholders to support increased awareness and education of comprehensive biomarker testing and precision medicine amongst patients, health care providers, and policymakers.

Loxo@Lilly

Loxo@Lilly is focused on removing barriers for patients with non-small cell lung cancer (NSCLC) to comprehensive next generation sequencing (NGS). Their plan has a 3-tiered approach: expand access to NGS through sponsored testing programs, generate data to support clinical utility of NGS, and partner with payers to generate evidence for coverage of NGS. Lilly's initiatives focus on traditionally underserved economic and racially diverse populations.

Potential Action Item for Stakeholders:

Loxo@Lilly's presentation was followed with active discussion around which step would be the most viable for their goals. It was decided amongst attendees that they and other interested stakeholders should focus on strengthening partnerships between payers and industry to provide access to coverage while evidence is being generated.

Facing Our Risk of Cancer Empowered (FORCE)

Staff from Facing Our Risk of Cancer Empowered (FORCE) discussed their efforts to address barriers Medicare patients face in obtaining genetic testing and preventive care. They acknowledge how the lack of coverage disproportionately affects low-income individuals and exacerbates health disparities. Their approach is addressing the current Medicare statute that only a person with “signs, symptoms, complaints, or personal histories of disease” meets criteria for Medicare coverage of medical services. Their goal is for Congress to revise the Medicare statute to provide coverage for germline testing for people with a family history of cancer to be tested even without a personal history of cancer, and for Congress to recognize the benefits of guideline-recommended early detection and preventative procedures and screening for those at risk of hereditary cancer and direct Medicare to provide coverage of those services to beneficiaries.

Potential Action Item for Stakeholders:

After their presentation and an engaging conversation with attendees, it was determined that the best route of action for FORCE and other interested stakeholders is to conduct targeted outreach to federal lawmakers.

Illumina

Illumina Market Access aims to demonstrate compelling value of next-generation sequencing (NGS) to payers supported by robust clinical and economic evidence in order to maximize and accelerate access to patients and improve health outcomes. Part of this effort includes addressing issues laboratories are facing as they seek coverage from payers for innovative NGS-based assays. Laboratories are required to spend time educating payers about the clinical utility and economic value of the tests they offer in seeking coverage. This process is lengthy, tedious and complex, and has specific requirements. The process is resource intensive in time, expertise and could cost thousands if a consultant is used during the process. As mentioned above, coverage and the lack thereof can be a huge hindrance to patient access. Illumina’s solution would be to have AMP create a coverage toolbox for classes of assays with coverage issues. The toolbox would include:

1. Systematic literature review,
2. Clinical Utility value statement with supporting evidence,
3. Economic utility with supporting evidence,
4. Cost modeling highlight cost consolidation, if applicable

Potential Action Item for Stakeholders:

For Illumina, attendee discussion agreed that Illumina and other interested stakeholders should work with coalitions, trade associations or others in the pharmaceutical space to help assist laboratories in increasing coverage.

Collective Action Item for Stakeholders Moving Forward:

Following a lively discussion amongst the participants, the group identified Loxo@Lilly’s idea for **“coverage with evidence development, partnerships between payers and industry to provide access**

while evidence is being generated” as the idea that the diverse stakeholders would focus on for the coming year. AMP and the other stakeholders plan to work closely with Loxo@Lilly to determine how each stakeholder group can help to support this goal. AMP anticipates hearing an update on the status of this action item at the 2023 Molecular Pathology Economic Summit.

Conclusion

The 2022 Economic Summit led to passionate discussion amongst attendees around the different barriers that patients experience when trying to obtain molecular diagnostic testing. A few key themes that emerged from this discussion include:

- The downstream impacts of the COVID-19 pandemic, including the diagnosis of cancers at later stages and laboratory supply and labor shortages.
- The complexity of the coding system and its inability to keep up with the evolving field of molecular diagnostics.
- The impact of pricing cuts to laboratories implemented by the Protecting Access to Medicare Act (PAMA).
- Patients unable to receive appropriate testing due to their insurance denials and coverage issues.

After thorough dialogue around these points, the group aligned around solutions, including:

- Advocacy regarding PAMA reform
- Broaden educational offerings and increase clinical decision-making support tools
- Streamline the coding system
- Increase communication between pathologists, clinical care providers, and patients.

AMP and other stakeholders left the Summit with a deeper understanding of these issues and potential solutions or action items to continue their advocacy work. AMP looks forward to continuing this conversation at the next Summit in 2023!

Appendix A: 2022 Summit Sessions

| Session Title | Session Type | Session Objectives |
|--|--------------------------|--|
| Welcome and Opening Remarks | Presentation | <ul style="list-style-type: none"> • Introduce moderators, speakers, and session topics. • Give overview of AMP and their policy and advocacy goals. |
| Real World Perspectives from Key Stakeholders: How the pandemic affected molecular diagnostic testing, the laboratories that perform these tests, and patient access | Facilitated Discussion | <ul style="list-style-type: none"> • Facilitated panel discussion featuring a variety of stakeholder groups around the impact of COVID-19 on the laboratory environment and patient access. |
| Real World Perspectives from Key Stakeholders: How CODING is a barrier for patient access | Facilitated Discussion | <ul style="list-style-type: none"> • Facilitated panel discussion featuring a variety of stakeholder groups around how coding is a barrier for patient access patient access. |
| Real World Perspectives from Key Stakeholders: How PRICING is a barrier for patient access | Facilitated Discussion | <ul style="list-style-type: none"> • Facilitated panel discussion featuring a variety of stakeholder groups around how pricing is a barrier for patient access patient access. |
| Real World Perspectives from Key Stakeholders: How COVERAGE is a barrier for patient access | Facilitated Discussion | <ul style="list-style-type: none"> • Facilitated panel discussion featuring a variety of stakeholder groups around how coverage is a barrier for patient access patient access. |
| Introduction to Afternoon Sessions | Presentation | <ul style="list-style-type: none"> • Introduction of the format of Innovation Lab |
| Innovation Lab – Part 1 | Interactive Presentation | <p>Stakeholders presented case examples and proposals:</p> <ul style="list-style-type: none"> • Cancer Support Community • Loxo@Lilly • Facing Our Risk of Cancer Empowered (FORCE) • Illumina |

| | | |
|--|--|--|
| <p>Innovation Lab – Part 2</p> | <p>Interactive Presentation</p> | <ul style="list-style-type: none"> • Attendees vote on the most promising Innovation Lab idea and the action items that they believe will have the most impact. • The moderator guided discussion on the next steps. |
| <p>Closing Remarks and Next Steps</p> | <p>Presentation</p> | <ul style="list-style-type: none"> • Discuss next steps and overarching themes. |