AMP

Association for Molecular Pathology

Molecular Pathology Economics Summit Summary

Economics Summit Summary

In 2019, the Association for Molecular Pathology (AMP) first gathered diverse stakeholders from the molecular diagnostics sector for a day-long Molecular Pathology Economics Summit (Summit) to discuss the rapidly evolving field of molecular diagnostics, including the frequently changing standards of care that challenge the current paradigm for medical coding, coverage, and payment. The Summit has fostered collaboration among stakeholders to identify actionable solutions to improve the economic landscape with the goal of developing stronger, more adaptable systems equipped to handle the ever-changing field of precision medicine.

The Fourth Annual AMP Economics Summit, held on August 16th, 2024, had the following objectives:

- Identify barriers to appropriate reimbursement for molecular pathology procedures;
- Examine the impact of these barriers on various stakeholders and patient access to care; and
- Propose potential solutions and/or novel approaches to overcoming barriers to implement shared policy goals from participating stakeholders in oncology, infectious diseases, and inherited conditions.

With representation from clinical laboratories, pharmaceutical companies, patient advocacy organizations, and diagnostic manufacturers, the first session focused on stakeholders' perspectives and approaches to the unique challenges associated with coding, coverage, and reimbursement of molecular diagnostics and their respective impacts on patient care. This discussion was followed by a presentation from a subject matter expert on the current legislative activities potentially influencing and affecting the economics of molecular pathology. Attendees also participated in breakout sessions aimed at identifying practical and applicable solutions for a variety of economic challenges. Each group provided several proposed action items for stakeholders to implement in the coming years.

AMP plans to host the Summit on an annual basis to foster discussion on concerning trends, new issues, potential solutions, and to highlight efforts that would advance the field of molecular pathology.

Panel Sessions: Perspectives from Stakeholders

Patient and Provider Community

This roundtable discussion revealed several critical themes around patient access, education, and coverage policies. Panelists identified significant access barriers to patients, including limitations such as insurance coverage and geographic locations that impact patient access among underserved and rural populations. Panelists also called for improved educational tools and clearer communication specifically for genetic testing, citing current test reports are too complex, which may make it difficult for providers to select the most appropriate treatment plan. Overall, this does not empower patients to advocate for themselves. Panelists also emphasized the need for consistent testing guidelines, federal coverage for hereditary cancer testing, and innovative solutions like telehealth, to bridge gaps in care. They identified streamlined, predictable coverage

processes and enhanced educational campaigns as potential solutions to improve patient outcomes and equity in care.

Pharmaceutical Community

Panelists highlighted the need for increased collaboration with diagnostic companies along with a better understanding of the important role diagnostic tests play in drug development. Additionally, the need to increase awareness of coverage policies was emphasized along with necessary improvements for implementation of new regulations (i.e., the Protecting Access to Medicare Act (PAMA), Food and Drug Administration (FDA) Final Rule on LDTs, etc). They stated it would be more useful for discussions to occur in the early stages of policy development between manufacturers and government agencies such as the FDA and the Centers for Medicare and Medicaid Services (CMS). The panelists also cited market consolidation pressures and the slow pace of updating guidelines as additional concerns. Potential actions to address these challenges included promoting partnerships between companies, streamlining regulatory processes, and enhancing consistency and access to diagnostics in patient care.

Manufacturer Community

Diagnostic manufacturers identified customer support, the FDA's Final Rule on LDTs, and venture capital investment as priorities. One panelist highlighted that NCCN guidelines include recommendations for the composition of molecular tests, without involving molecular pathology as subject matter experts. This concerned many stakeholders. Panelists also expressed restrictive testing regulations, inadequate insurance coverage, and insurance denials all of which contribute to restricted patient access to care. They added that the uncertainty and confusion created by the FDA Final Rule on LDTs has introduced additional barriers including delays, as many manufacturers are already slowing, some halting, projects in the pipeline due to ambiguous compliance requirements at this point in time. The panelists mentioned venture capitalists have also slowed down investment from the rates seen in 2020; however, they suggested that the increasing use of AI in diagnostics might influence future trends and investments. The participants identified the need to better integrate laboratory testing into healthcare, by addressing a recurring challenge to educate payers on the value of molecular testing and its direct connection to improved patient outcomes. The diagnostic manufacturer session concluded with participants highlighting Telehealth, Artificial Intelligence (AI) and clinical decision support as the next breakthroughs in molecular diagnostics.

Clinical Laboratory Community

The panelists in this discussion focused on several topics, including reimbursement of molecular testing, the impact of the FDA Final Rule regulating LDTs, administrative costs, economic decision-making in the laboratory, and patient engagement. The panelists expressed concern with reimbursement policy; particularly, with the AMA CPT code process influences the development of lab tests, i.e., should a specific test be more likely to be reimbursed, laboratories will validate to meet the CPT code descriptions. Many participants mentioned that payers are requiring laboratories to meet different standards or require unique coding for laboratories to receive payments. This is highly burdensome on laboratories and can cause delays in payment, or for some labs, resulting in no payment at all despite the completed work and resources used. Panelists also cited the FDA Final Rule on LDTs as a major concern, particularly noting how it would tremendously

increase costs for test development compounded by inadequate reimbursement, which would directly impact innovation. The panelists also touched on the need for CMS to improve transparency for how the CLFS Annual Payment Determination Process determines crosswalks and how the NCCI edits are only given to a select few stakeholders to review before the edits are published. Proposed legislation addressing stakeholder concerns with molecular pathology economics, such as SALSA, and Prior Authorization were mentioned. Looking ahead, there was optimism about integrating clinical decision tools and payers and the public recognizing the value of laboratory tests, though some anticipated a more consolidated and less innovative industry in the future.

Congressional Action on Laboratory Test Pricing, Coverage, and Reimbursement: Trends and Outlook

Lindsey Trischler, Principal at Innovation Policy Solutions, presented current congressional priorities and legislation relevant to the *Economics Landscape of Precision Medicine*.

In addition to the Fiscal Year 2025 government funding bills, the presentation noted the following policies:

- The Saving Access to Laboratory Services Act (SALSA): This legislation would reform PAMA and create a sampling method for "widely available tests." If this bill is not enacted, or if Congress does not pass future delays to PAMA's requirements, laboratories will undergo another round of reporting and cuts. (Note: Congress passed a one-year PAMA delay on September 25th as a part of a continuing resolution)
- Medicare's Transitional Coverage for Emerging Technologies (TCET) Rule: This rule establishes a pathway using the national coverage determination and coverage development processes to expedite Medicare coverage of certain FDA-designated breakthrough devices. However, legislation introduced in the House called the Ensuring Patient Access to Critical Breakthrough Products Act reimagines the program nearly guaranteeing that FDA-designated breakthrough devices would receive four years of transitional Medicare coverage if enacted.
- Medicare Multi-Cancer Early Detection Screening Coverage Act (MCED): This bill is a bipartisan, bicameral bill that would establish a benefit category for multi-cancer early detection tests with FDA authorization.
- Improving Seniors' Timely Access to Care Act: This bill would increase transparency around Medicare Advantage plans' prior authorization (PA) requirements, clarify CMS' authority to establish a timeline for electronic PA requests. Expand beneficiary protections and require HHS and other agencies to report to Congress on program integrity efforts.
- Telehealth: In January 2025, waivers and regulatory flexibilities allowing expanded use of telehealth during the COVID-19 public health emergency will expire, including geography, site of service, and practitioner type. Despite strong support for making these flexibilities permanent, Congress has not yet passed the legislation due to concerns about how it would increase costs to the Medicare program.

Breakout Sessions: Identifying Challenges and Solutions

Attendees formed four small groups focused on the following topics:

- Coding and Pricing Economics
- The Role of Artificial Intelligence in Economics
- Coverage Polices
- The Economic Impact of the FDA Final Rule, Medical Devices; Laboratory Developed Tests

Coding and Pricing Economics

Coding and pricing is an intrinsic part of the economics landscape of Molecular Pathology. Molecular Pathology codes have been increasingly added to the AMA CPT code book since the first codes were added in 2014. This breakout group investigated the issues surrounding molecular testing code usage and identified solutions to these issues.

Issues Identified:

1. Lack of transparency around the development of CPT codes and NCCI edits.
2. The CMS CLFS payment determination process is a barrier to new tests reaching the market as it only occurs once a year.
3. The timeline between the last AMA CPT Editorial Panel meeting and the CMS CLFS pricing exercise is too short to adequately provide thoughtful recommendations.

Solutions:

1. Advocate that the AMA and CMS increase transparency to stakeholders around the AMA CPT editorial panels' deliberations and the NCCI edits, respectively.
2. Request the CMS pricing exercise occur twice a year to better keep up with new innovations.
3. Advocate for a 4-month cut-off between the last AMA CPT editorial panel meeting and the CMS CLFS pricing exercise.

The Role of Artificial Intelligence

Artificial intelligence is a rapidly evolving technology that is entering the molecular diagnostic sphere. Many tests are being developed to use AI in their algorithms or processes. Participants discussed the potential issues in using AI for molecular testing (i.e. validation of tests) and how to best streamline its use in this area.

Issues Identified:

1. Current FDA guidance is inadequate, and the traditional regulatory pathway for software will not be sufficient to address the complexities of AI.
2. The use of AI in clinical trials could create biases towards certain subgroups.
3. The technology is complex and may be difficult to identify when algorithms "make a wrong turn."

Solutions:

1. Regulation needs to allow for iterative improvements that account for validation that has already been done.
2. Increased collaboration with diverse and underrepresented populations to address biases in clinical trials
3. Advocate for more experts in the field to validate and evaluate these new technologies.

Coverage Policies

Public and private payers' coverage policies are often confusing, inconsistent, and the processes to develop them lack transparency. The breakout group identified ways for stakeholders to engage and educate payers on new standards of care in efforts, and work with providers to better understand coverage policies.

Issues Identified:

1. Payers find the language in clinical practice guidelines too confusing.
2. Preventive testing is seen as too expensive by payers and therefore, is not covered.
3. Providers are unaware of the intricacies of coverage of molecular testing. As a result, providers may order tests they know will be covered instead of those that are most clinically appropriate.

Solutions:

1. Participants proposed stakeholder collaboration to simplify guideline language, clarify what is preferred in molecular testing and what is required so it is clearer to payers and patients to comprehend and advocate for themselves. Laboratories could develop partnerships with payers to leverage clinical support tools.
2. Stakeholders should partner to collect data that demonstrates cost savings associated with preventative testing.
3. Integration of coverage policies in electronic health records could help providers better understand what tests are covered along with patient cost sharing responsibilities.

The Economic Impact of the FDA Final Rule, Medical Devices; Laboratory Developed Tests

On May 6th, 2024, the FDA published a final rule, "Medical Devices; Laboratory Developed Tests". This rule modified the definition of in vitro diagnostic to include laboratories as manufacturers and thereby subject laboratory developed tests to medical device regulatory requirements.

Issues Identified:

- The FDA grossly underestimated the compliance costs and administrative burdens for laboratories to with the rule. Many laboratories will be unable to afford these associated costs which will significantly impact patient access to testing
- There has been a lack of transparency from the agency regarding compliance requirements.
- The uncertainty around various aspects of the rule has already delayed innovation and prevented laboratories from adding new tests to their menus.

Solutions:

- Advocate for a legislative solution to regulate LDTs that takes a more “middle of the road” approach to that better reflects the nuances of the field.
- Laboratories should prepare as though the rule will be implemented and seek the advice of licensed counsel or certified regulatory affairs specialists.

Conclusion

The AMP 2024 Molecular Pathology Economics Summit provided a forum for participants to analyze the economic aspects of medical coding, coverage, and reimbursement, as well as understand the challenges faced by different stakeholder groups. The morning roundtable discussions highlighted several challenges which were addressed in greater detail during the afternoon breakout groups. Participants identified solutions, which centered around the overall increase in transparency at various levels within the regulatory and private sector frameworks including coding, and coverage decision-making processes and developing partnerships with public and private payers to provide the most current scientific information on the updated guideline recommendations. These solutions will require a holistic approach among all stakeholders to achieve these solutions.

AMP looks forward to the implementation of proposed action items and continuing this conversation at the next Summit!