AMP

ASSOCIATION FOR MOLECULAR PATHOLOGY

Molecular Pathology Economics Summit

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Introduction

Molecular diagnostics is a rapidly evolving field with frequently changing standards of care that challenge the current paradigm for medical coding, coverage, and payment. In 2019 and 2022, the Association for Molecular Pathology (AMP) brought diverse stakeholders from the molecular diagnostics sector together for a day-long Molecular Pathology Economics Summit (Summit) to address various economic challenges and provide actionable solutions. The Summit has successfully served as a platform to foster collaboration among stakeholders tasked with improving the economic landscape from within to develop stronger, more adaptable systems equipped to handle changes in precision medicine.

On September 13th, 2023, AMP hosted the third Economics Summit with the following objectives:

- Identify and analyze the aspects of coding, pricing and reimbursement that create barriers to patient access.
- Discuss potential solutions to those barriers and provide practical, interdisciplinary action items to implement across the sector.

AMP was pleased to facilitate this event and sought to have broad stakeholder input, which consisted of 60 individuals representing diagnostic manufacturers, pharmaceutical companies, trade associations, professional organizations, clinical laboratories, and patient advocacy groups. The Summit was divided into three sessions. The first focused on various stakeholder perspectives with representation from clinical laboratories, pharmaceutical companies, patient advocacy organizations, and diagnostic manufacturers and their respective approaches to the unique challenges associated with molecular diagnostic coding, coverage, and reimbursement. These interactive, candid conversations explored barriers and potential solutions to patient access. AMP also held breakout sessions to identify shared policy priorities which allowed stakeholders to determine practical and applicable solutions. Each of the four groups provided several proposed action items for stakeholders to implement in 2024. The third session, led by AMP, facilitated discussions on the future of molecular pathology including artificial intelligence.

Summarized below are the barriers, potential solutions, and proposed action items suggested for implementation by stakeholders at the 2023 Summit. AMP continues to host the Summit on a yearly basis to discuss concerning trends, new issues, potential solutions and highlight efforts that would benefit the field of molecular pathology. AMP will continue to advance conversations toward improving patient access to appropriate molecular diagnostic testing and will actively update Summit attendees on progress towards these goals at the 2024 Summit.

Facilitated Discussion Morning Sessions Key Themes

In these sessions, participating stakeholders were split into four categories: clinical laboratories, patient advocate organizations, pharmaceutical companies, and diagnostic manufacturers to obtain their unique perspectives on shared economic challenges.

Uncertainty in Reimbursement

During the COVID-19 pandemic, the field of molecular pathology adapted to enormous shifts affecting economic, administrative and workflow processes that have caused significant unprecedented burdens on laboratories across the country. Repercussions from the pandemic remain problematic for the molecular diagnostics industry.

There are a growing number of barriers that laboratories must overcome to receive reimbursement.

Clinical laboratory stakeholders spoke to the unreliability of reimbursement for tests. As there is no guaranteed payment, a laboratory may have to incur a significant cost burden in order to provide proper patient care and maintain patient access to testing. This has set a precedent for laboratories: either offer testing and risk incurring high costs to the lab, or refrain from testing and reduce patient access to care.

Clinical laboratory stakeholders noted current reimbursement levels are inadequate to keep up with the innovations in the field and these levels do not account for the indirect costs associated with running a laboratory. Additionally, laboratories are not incentivized to create new innovative tests that better benefit patients due to concerns with receiving reimbursement from payers that would reflect the work and resources associated with performing a new test. Moreover, reimbursement rates also fluctuate among private payers, which can make it difficult for laboratories to keep track of their bottom line. This impact is especially significant for smaller laboratories that lack administrative resources such as a designated billing department. Further exacerbating this issue is a lack of molecular professionals in the work force following the COVID-19 pandemic. Smaller laboratories also often struggle with employee attrition due to larger, commercial laboratory competitors that can offer higher salaries.

Stakeholders representing the pharmaceutical industry shared similar concerns and noted they received information from physicians that underscored extreme hesitancy from many doctors when ordering a test due to its cost. Given the unclear designation for the responsible party shouldering the cost of a test, physicians sometimes entirely forgo ordering costly tests for patients. Patient advocacy stakeholders noted that patients are often unaware of these reimbursement barriers that impact access to care. Oftentimes, if there is a problem in the ordering of testing, laboratories are absorbing the cost of the test to provide a needed diagnosis to a patient.

An additional strain that was cited by stakeholders representing clinical laboratories and diagnostic manufacturers is the implementation of the Protecting Access to Medicare Act of 2014 (PAMA). PAMA significantly reformed the Medicare payment system for clinical diagnostic laboratory tests and generally requires that Medicare payment for clinical diagnostic laboratories be based on the weighted median of reported private payer rates. The median prices for reimbursement were originally set by Centers for Medicare and Medicaid Services (CMS) using data collected mostly from high volume

laboratories, which did not account for the diversity of laboratories in the United States and the differing reimbursement rates at various institution types. The first round of PAMA's reimbursement cuts negatively impacted laboratory reimbursement, and stakeholders are concerned that without Congressional intervention, test reimbursement will be lower than the cost of running the test. While the clinical laboratory stakeholders acknowledged Congress has delayed PAMA reporting requirements and significant payment cuts over the last several years, this solution is temporary and unsustainable. In addition, the downstream effects of continued delays instead of a more stable legislative solution would disproportionately affect community-based institutions along with those in rural areas, which would likely be forced to stop offering certain tests altogether. This in turn may force the industry to restructure and laboratories to consolidate. Stakeholders noted that in this future potential scenario many hospitals would have to send out tests to reference laboratories, which can significantly delay turnaround times for results and patient care.

Current Medical Coding System Lacks Transparency, Standardization

The burgeoning field of molecular diagnostics has seen rapid transformation over the last several decades—what was once novel has now become the standard practice for clinical care. With these advances, the American Medical Association (AMA) Current Procedural Terminology (CPT) coding system which provides a uniform nomenclature for medical services and procedures rendered, also has been required to evolve to meet the needs of clinical laboratories.[1] While there are processes to develop new molecular codes, it can take 12 to 18 months for a code to be published on the Clinical Laboratory Fee Schedule (CLFS).

The AMA has worked to develop CPT codes to accurately describe the work of molecular pathology, but there have been many challenges. Stakeholders from clinical laboratories, pharmaceutical and diagnostic manufacturer companies noted technological innovations in the molecular space often do not have a comparable code that can be used to determine proper pricing more easily by CMS. Generally, when evaluating a new code, CMS can set pricing for reimbursement based on an existing code for testing that involves a similar amount of work and resources through a process known as "crosswalking." For new codes, if there is no appropriate comparable code already in existence, CMS will go through the "gapfill" process. The payment rate for these codes are established in conjunction with regional Medicare Administrative Contractors (MACs) that report local payments and use this data to calculate the median. This process, while necessary at times, results in delays in code implementation.

With respect to the coding system, AMP notes that CMS also created the National Correct Coding Initiative (NCCI) to promote correct coding methodologies nationwide and reduce improper coding, with the overall goal of reducing improper payments of Medicare Part B and Medicaid claims.[2] The NCCI provides quarterly updates and seeks input on an invitation-only basis from a few professional associations. Clinical laboratory and diagnostic manufacturer stakeholders are among those without access to this information prior to publication. They view this exclusion as detrimental to the entire

[1] https://www.ama-assn.org/topics/cpt-codes
[2] https://www.cms.gov/national-correct-coding-initiative-ncci\

coding process. The inability to provide feedback coupled with the lack of transparency forces these stakeholders to wait for new edits to be formally released by CMS, which leaves clinical laboratories and manufacturers susceptible to surprise edits that would negate ability to code adjacent, necessary procedures.

Attempts to streamline both the coding and reimbursement processes have been historically unsuccessful according to clinical laboratory, pharmaceutical, and diagnostic manufacturer stakeholders. They cited a recent uptake of payers using different coding systems, such as the Z code system offered by the Molecular Diagnostic Services (MolDX) Program, as being particularly problematic.

AMP recognizes that the MolDX Program seeks to clearly identify the test performed on a claim using Z codes which uniquely identifies each test, allowing the payer to precisely identify what service was rendered. AMP notes there has been a recent trend among private payers that are requiring Z codes but anticipates difficulties for laboratories located outside of the MolDX jurisdiction to adapt to these requirements associated with obtaining a Z code. Additionally, AMP is concerned that this will increase requests for technical assessments (TAs) which establish the clinical utility of a test. Among clinical laboratory and pharmaceutical stakeholders, these new Z code requirements have led to confusion, especially given that payers are implementing slightly different guidelines as compared to the MolDX program. This coding variability, according to clinical laboratory stakeholders, has also contributed to administrative staffing burdens in clinical laboratories, as institutions must work diligently to ensure that coding is being done properly to meet each individual payer's requirements. Clinical laboratory stakeholders believe this burden will only be exacerbated as clinical laboratories begin to face additional hurdles imposed by Laboratory Benefit Managers (LBMs) and prior authorization requirements.

Coverage and Reimbursement of Molecular Testing Falls Short, Harms Patients

Stakeholders from clinical laboratories also stated that coding and reimbursement challenges are also intricately linked to obtaining coverage for molecular testing. This integration was also recognized by those from pharmaceutical companies and diagnostic manufacturer industry. One concern pertaining to coverage was the difficulty for coverage policies to keep up with guidelines that reflect the latest technologies used currently for the standard of care. Clinical laboratories, pharmaceutical companies and diagnostic manufacturers attributed this to the payers' lack of in-depth knowledge and/or understanding of the important role molecular testing plays in patient care.

One example discussed was the lack of coverage for Dihydropyridine dehydrogenase (DPYD) testing despite widespread agreement that there is clinical utility for DPYD testing. The DPYD test is a pharmacogenetic test which detects genetic variations that influence a patient's ability to metabolize fluoropyrimidines, a class of chemotherapies used to fight cancer. People with certain genetic variants are at a higher risk experiencing severe, life-threatening toxicity which can lead to death and stakeholders are concerned that the lack of reimbursement for testing is preventing patients from accessing critically important information that could inform their treatment decisions.

Another reimbursement barrier identified by clinical laboratories is the implementation of a third-party validation system for laboratory tests. Many payers have implemented these systems and the additional work required has caused a significant administrative burden for laboratories throughout the country. Laboratories are also not guaranteed reimbursement, despite completing the required documentation. Stakeholders from the clinical laboratory, manufacturers, and pharmaceutical companies expressed concern for how this system will impact coverage of tests in the future.

Equitable Patient Access to Testing

The clinical laboratory stakeholders expressed concern that providers are ordering tests that are not comprehensive, which prevents the most efficient care from being provided. Even when a new technology has demonstrated clinical utility, it can still be several years before the technology is covered and patients can have reliable access. Diagnostic manufacturers and pharmaceutical stakeholders echoed these sentiments, noting that the lack of coverage disincentivizes the development of new technologies given the unclear pathway to obtain coverage once a technology is developed. Patient organization representatives also mentioned that many patients learn about new technologies and request new treatment options, but again, due to a lack of coverage providers may be hesitant to order tests out of concern for cost that may be passed on to the patient.

Patient advocacy organizations spoke to the increasing disparities for patient access to molecular testing at rural and community cancer centers, and academic medical centers which will grow as tests increase in complexity. The stakeholders identified a variety of factors contributing to testing disparities across the country. Patient advocate organizations cited patients utilizing smaller community centers do not have as much access to testing given that physician resources are strained and there is little time to communicate with the insurance companies. Patient advocacy organization stakeholders also highlighted another testing disparity was due to hospital's reliance upon contracts and the ability of that health system to easily administer testing in a particular region.

Another issue identified was hesitancy from both providers and patients given the reality that the patient may not be able to afford the testing due to a lack of coverage or education to navigate the complex reimbursement system. Stakeholders representing pharmaceutical companies mentioned that they have programs to help improve the accessibility of companion diagnostics; however, very few laboratories have used the program. All stakeholders agreed that ensuring access for rare disease testing by advocating for fair, rational reimbursement should be a priority.

Breakout Sessions: Navigating the Future Economic Challenges of Precision Medicine

Potential Solutions & Proposed Action Items

Following the facilitated discussion sessions, the summit attendees split into four breakout groups to discuss potential implementable solutions and propose action items to address challenges impacting the economics of molecular pathology. Each group was led by a member of the AMP Economics Summit Planning Committee. The groups were charged with identifying problems associated with an assigned topic and providing achievable action items that stakeholders could implement in the next year. Following the breakout discussions, the groups reconvened and presented their solutions and proposed action items to all attendees. The deliberations and proposed action items are summarized below.

Group 1—The Public: Ensuring the Perception of the Quality of Molecular Diagnostic Tests

This breakout group analyzed the current public perception of molecular diagnostic tests and discussed how the general public is not aware of the importance of laboratory operations which ensure patients receive the best available care.

Proposed action items for all stakeholders:

- Provide transparency regarding molecular test quality at your institutions.
- Utilize trusted partner channels, such as medical associations or patient advocate groups to communicate and educate the general public about the measures in place to ensure accurate and reliable molecular diagnostics testing.
- Engage with “power brokers” (e.g. hospital administrators, insurance providers, legislators) to provide them with a greater understanding of existing controls and assurances used to ensure high quality testing is performed.

During the broader discussion with Summit attendees, these proposed action items were endorsed by participants who felt these steps are appropriate to address misconceptions of the public perception of molecular diagnostic tests. The participants also emphasized the need for increased transparency for the public to better understand the field of molecular diagnostics and recognize the important role testing plays in patient care. Overall, participants believed that these action items will help overcome barriers for patients to understand and access molecular testing.

Group 2—Private Payer Policies: Creating Space for Labs to Provide Feedback to Private Payer Policies

This breakout group examined ways to improve the private payer coverage determination process and particularly the lack of collaboration with laboratories. Several coverage policies have negatively impacted laboratory testing. Therefore, it was suggested that private payers collaborate with molecular pathology experts during the creation and development of coverage policies.

Proposed action items for all stakeholders:

- Establish a private payer coverage policy review process.
- Establish AMP as a partner for coverage policy development for private and public payers.
- Engage with Laboratory Benefit Managers (LBMs) to inform their evidence review processes.
- Meet with private payers.

The Summit attendees were in favor of these proposed action items. AMP members present at the Summit highlighted the organization's efforts to engage with private payers to better understand their concerns through AMP's Payer Engagement Working Group. Others touted the benefits of collaborating and building trust with private payers to ideally create a pathway that would establish a process for stakeholders to provide feedback on new coverage policies. It was suggested that this could be achieved by convening regular meetings between multiple stakeholders and individual private payers. In the past, AMP has reviewed private payer coverage policies, however these were indirect requests, which suggests more private payer education is needed. Strengthening relationships with private payers would help to increase payers' understanding around molecular diagnostic testing and may help future coverage policies.

Group 3—The Practice of Molecular Diagnostics for Payers: Payer Education and Engagement

This breakout group identified ways for stakeholders to engage and educate payers on new standards of care in efforts to reverse trends of increasing third party validation requirements. It was noted that many payers have difficulty with creating molecular pathology policies as they may have limited in-house expertise.

Proposed action items for all stakeholders:

- Create a forum for multiple stakeholders to engage directly with payers and Laboratory Benefit Managers (LBMs) to discuss evidence requirements.
- Engage employer groups to put pressure on the payers.
- Create model coverage policies to educate payers.
- Use public relations tactics to inform the public and put pressure on the payers.

Summit attendees were generally in favor of the identified action items, but one person also noted the need for engagement with self-insured employers who may not be part of larger insurance coalition. The participants were incredibly supportive of forming a coalition to create model coverage policies and conveyed enthusiasm about the possibility of collaboration in this area.

Group 4—Coding: Streamlining the Coding System

This breakout group assessed the difficulties stakeholders have with adhering to the various coding systems and identified ways to overcome these barriers.

Proposed action items for stakeholders:

- Conduct a legal analysis of MolDX practices and how the coding requirements impact CLFS payment rates.
- Advocate for NCCI to utilize a public notice and comment approach; increase transparency for Procedure-to-Procedure edits and Medically Unlikely Edits

Summit attendees also agreed with the group's concerns regarding MolDX and NCCI edits. Many are concerned with the proliferation of private payers requiring the use of MolDX Z codes, adding that PAMA is dependent on laboratories reporting their cost for testing in conjunction with a CPT code. According to clinical laboratory, pharmaceutical, and diagnostic manufacturer stakeholders, the use of Z codes is predicted to further increase the use of the unlisted molecular pathology procedure code 81479 given that MolDX encourages the use of 81479. The consequence of increased use of 81479 recognized by these stakeholders, is that fewer laboratories would report data to CMS about the use of *other* CPT codes, resulting in skewed data which would lead to inaccurate pricing. These stakeholders showed interest in understanding the legal ramifications surrounding the use of Z codes and the effects this usage would have on the establishment of Medicare payments under PAMA. Stakeholders also agreed the NCCI edits have a large impact on coding and were supportive of the American Clinical Laboratory Association's (ACLA) efforts on draft legislation that would require NCCI edits to go through a notice and comment period before being finalized.

Facilitated Discussion Afternoon Session: The Future of Molecular Pathology: The Next Decade

Mary Williams, former Executive Director of AMP, led a discussion with AMP leadership to evaluate the future of Molecular Pathology.

The next decade for Molecular Pathology will no doubt be interesting. As medical and technological advances are made, increased awareness, knowledge and understanding of molecular pathology will also follow suit. Stakeholders noted that pressures on molecular diagnostic laboratories will become stronger with increasingly complex testing. It was also emphasized that the field of molecular pathology must stay transparent in order to remain a trusted entity in medicine and diagnostics.

The workforce shortages within the field were exacerbated by the pandemic, but many molecular pathologists are also reaching retirement age, which begs the question, to what degree will artificial intelligence (AI) or machine learning (ML) support the work of laboratory professionals? Participants pointed out the continuously increasing complexity of the data will make it difficult to use AI/ML alone and there will remain a reliance on professionals in the laboratory work flow.

Overall, participants were very hopeful for the future of molecular pathology and its tremendous capacity to improve health care; however, it was acknowledged that with new technologies comes new complex issues.

Conclusion

The 2023 Economics Summit provided a platform for diverse stakeholders to analyze economic aspects of medical coding, coverage and reimbursement. Participants formulated solutions that included several proposed action items that can be implemented and achieved within clinical laboratories, patient advocate organizations, pharmaceutical industry and diagnostic manufacturer companies. Highly engaged participants are committed to accomplishing this shared vision.

Key themes that emerged from this discussion include:

- Payers have difficulty keeping pace with innovations in molecular pathology and evidence development. There is often a significant delay in information being incorporated into coverage policies.
- Reimbursement uncertainty impacts laboratories' ability to offer testing, can affect patient access dramatically
- Laboratories have been harmed by pricing cuts that have occurred due to PAMA.

After thorough dialogue, the group chose three main priorities:

- Increase engagement and collaboration with private payers to develop coverage policies.
- Transparency in coding system implementation is necessary to equitably prepare stakeholders and prevent surprise edits.

AMP and other stakeholders left the Summit with a deeper understanding of economic challenges proposed action items. AMP looks forward to the implementation of proposed action items continuing this conversation at the next Summit in 2024!

Appendices

Appendix A: 2023 Summit Sessions

Session Title	Session Type	Session Objectives
Welcome and Opening Remarks	Presentation	• Introduce moderators, speakers, and session topics. • Give an overview of AMP and their policy and advocacy goals.
Session One, Real World Perspectives: Clinical Laboratories	Facilitated Discussion	• Facilitated panel discussion featured laboratory stakeholders around reimbursement, coding, and coverage.
Real World Perspectives: Patient and Provider community	Facilitated Discussion	• Facilitated panel discussion featured patient advocates and provider stakeholders around reimbursement, coding, and coverage.
Real World Perspectives: Diagnostic Manufacturers	Facilitated Discussion	• Facilitated panel discussion featured manufacturer stakeholders around reimbursement, coding, and coverage.
Real World Perspectives: Pharmaceutical Companies	Facilitated Discussion	• Facilitated panel discussion featured pharmaceutical stakeholders around reimbursement, coding, and coverage.
Introduction to Afternoon Sessions	Presentation	• Introduction of the format of breakout groups
Session Two, Breakouts: Navigating the Future Economic Challenges of Precision Medicine	Small Group Discussions	• Small groups featured topics to address different economic impediments. Each group developed solutions and proposed action items
Identifying Solutions and Action Items	Facilitated Discussion	• Presentation of potential solutions and proposed action items to Summit attendees, followed by facilitated discussion.
Session Three: Looking to the future	Facilitated Discussion	• Facilitated panel discussion of AMP leadership that addressed the upcoming molecular pathology innovations, artificial intelligence, and the future of molecular pathology.
Closing Remarks and Next Steps	Presentation	• Discussed next steps and overarching themes.

Appendix B: Breakout Group Action Items

Breakout Group	Action Items
Public Perception of the Quality of Molecular Tests	• Provide transparency regarding molecular test quality at your institutions. • Utilize trusted partner channels, such as medical associations or patient advocate groups to communicate and educate the general public about the measures in place to ensure accurate and reliable molecular diagnostics testing. • Engage with "power brokers" (e.g. hospital administrators, insurance providers, legislators) to provide them with a greater understanding of existing controls and assurances used to ensure high quality testing is performed.
Private Payer Policies	• Establish a private payer coverage policy review process. • Establish AMP as a partner for coverage policy development for private and public payers. • Engage with Laboratory Benefit Managers (LBMs) to inform their evidence review processes. • Meet with private payers.
Payer Education and Engagement	• Create a forum for multiple stakeholders to engage directly with payers and Laboratory Benefit Managers (LBMs) to discuss evidence requirements. • Engage employer groups to put pressure on the payers. • Create model coverage policies to educate payers. • Use public relations tactics to inform the public and put pressure on the payers.
Streamlining the Coding System:	• Conduct a legal analysis of MolDX practices and how the coding requirements impact CLFS payment rates. • Advocate for NCCI to utilize a public notice and comment approach; increase transparency for Procedure-to-Procedure edits and Medically Unlikely Edits