AMP

Association for Molecular Pathology

Molecular Pathology Economics Summit

September 20, 2019

Washington, D.C.

AMP Association for Molecular Pathology

AMP 2019 Molecular Pathology Economics Summit

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AMP Molecular Pathology Economics Summit

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Agenda at a Glance

Friday, September 20, 2019 – The Conrad, Conservatory Ballroom A&B, Washington, D.C.

7:30 am	**Registration and Breakfast** *(Gallery Conservatory B)*
8:00 am	Welcome and Opening Remarks
8:15 am	Real World Perspectives from Key Stakeholders: Clinical Laboratories
9:00 am	Real World Perspectives from Key Stakeholders: Patient and Provider Community
9:45 am	**Coffee Break** *(Gallery Conservatory A)*
10:15 am	Real World Perspectives from Key Stakeholders: Manufacturer Community
11:00 am	Real World Perspectives from Key Stakeholders: Pharmaceutical Community
11:45 am	**Lunch** *(Gallery Conservatory A)*
12:15 pm	Lunchtime Presentation: AMP Economic Affairs Committee Coding Coverage and Reimbursement Strategies
12:45 pm	Real World Perspectives from Key Stakeholders: Identified Key Themes
1:15 pm	Facilitated Discussion: Identifying High Impact Solutions
1:45 pm	**Coffee Break** *(Gallery Conservatory A)*
2:15 pm	Facilitated Discussion: Exploring Novel Options for Collaboration
3:00 pm	Closing Remarks and Next Steps
3:30 pm	**Departure**

Main Program

Friday, September 20, 2019

7:30 am — **Registration and Breakfast**

The Conrad Washington D.C., Gallery Conservatory B, Level 2
950 New York Ave. NW
Washington, DC, 20001

8:00 am — **Welcome and Opening Remarks**

Conservatory Ballroom A&B, Level 2

Speaker: **Samuel Caughron**, MD, Chair, AMP Economic Affairs Committee, *MAWD Pathology Group, P.A.*

8:15 am — **Real World Perspectives from Key Stakeholders: Clinical Laboratories**

Facilitator: **Amy Miller**, PhD

Multiple stakeholders from different industries are affected by the economic challenges plaguing clinical molecular diagnostics. Each industry and stakeholder is uniquely impacted, but there is common alignment around an interest in improving the overall economics for diagnostic testing. Advances in diagnostic testing and closely related therapies are driving precision medicine, while at the same time continuing to challenge current paradigms for molecular diagnostic coding, coverage and reimbursement. During the morning session, a series of roundtable discussions will be held, each focused on a specific stakeholder perspective including clinical laboratories, pharmaceutical companies, in vitro diagnostic manufacturers, and patient advocacy groups. Interactive candid discussions will explore the unique challenges confronting each of these stakeholder groups, with the ultimate goal of mutual understanding and identification of common areas in which to assign resources to improve the economics in pursuit of best patient care.

Pre-summit contemplation of the following questions will assist in framing the conversations:

- What are the biggest economic issues in molecular diagnostics that are barriers for your organization or members? Consider commenting on issues such as:
  - PAMA reform; Laboratory Benefit Managers; coding; NCCI edits; National Coverage Determination for Next Generation Sequencing for Advanced Cancer; coverage criteria (*i.e.*, "clinical utility"), etc.

- Are there aspects of molecular diagnostic testing reimbursement where stakeholders have been their "own worst enemy?"
- Within the stakeholder community, where is there the biggest disconnect between established reimbursement policy and actual clinical practice? What negative impact has it had?
- How is the regulatory landscape affecting laboratory economics?

9:00 am

Real World Perspectives from Key Stakeholders: Patient and Provider Community

Facilitator: **Amy Miller**, PhD

The facilitator will lead a discussion with panel members representing each stakeholder group to identify common issues of concern.

9:45 am

Coffee Break

Gallery Conservatory A, Level 2

10:15 am

Real World Perspectives from Key Stakeholders: Manufacturer Community

Conservatory Ballroom A&B, Level 2

Facilitator: **Amy Miller**, PhD

The facilitator will lead a discussion with panel members representing each stakeholder group to identify common issues of concern.

11:00 am

Real World Perspectives from Key Stakeholders: Pharmaceutical Community

Facilitator: **Amy Miller**, PhD

The facilitator will lead a discussion with panel members representing each stakeholder group to identify common issues of concern.

11:45 am

Lunch

Gallery Conservatory A, Level 2

12:15 pm

Lunchtime Presentation: AMP Economic Affairs Committee Coding, Coverage and Reimbursement Strategies

Conservatory Ballroom A&B, Level 2

Speakers: **Samuel Caughron**, MD, Chair, AMP Economic Affairs Committee, *MAWD Pathology Group, P.A.*

Pranil Chandra, DO, Vice-Chair: Coverage Decisions, AMP Economic Affairs Committee, *PathGroup, LLC*

Anthony Sireci, MD, MSc, Vice-Chair: New Codes and Pricing, AMP Economic Affairs Committee, *Loxo Oncology*

Leaders for the AMP Economic Affairs Committee will present the current and future advocacy resources, strategies, opportunities and objectives of the AMP Economic Affairs Committee in the areas of coding, coverage and pricing. The speakers will highlight past successes and lessons learned through advocacy efforts and answer questions from participants.

12:45 pm

Real World Perspectives from Key Stakeholders: Identified Key Themes

Facilitator: **Amy Miller**, PhD

The facilitator will lead a discussion with panel members representing each stakeholder group to unpack the themes revealed in the roundtable discussions.

1:15 pm

Facilitated Discussion: Identifying High Impact Solutions

Facilitator: **Amy Miller**, PhD

Participants will join in discussion on how the themes from the morning session can be addressed through stakeholder's advocacy activity. The objective of this session is to identify potential policy solutions on which stakeholders can align in allocating resources to improve molecular diagnostic testing coding, coverage, and/or pricing, whether it is through individual or collaborative approaches.

The following questions will assist in framing the conversation:

- Are there achievable novel approaches that should be considered in order to achieve the desired outcomes?
- How can we best work to ensure patient access to molecular diagnostic testing throughout the healthcare system?
- Is it possible to achieve a commitment to action from the stakeholders in the room?

1:45 pm	**Coffee Break** *Gallery Conservatory A, Level 2*
2:15 pm	**Facilitated Discussion: Exploring Novel Options for Collaboration** *Conservatory Ballroom A&B, Level 2* Facilitator: **Amy Miller**, PhD The unique diversity of stakeholders participating in this event allows for innovative discussion about potential new ways to align interests and incentives. During this session, attendees will explore the limitations of existing mechanisms for collaboration between stakeholders and share new ideas for interaction that could positively influence the economic landscape of molecular diagnostic testing while being acceptable to regulators, payors and other interested third parties.
3:00 pm	**Closing Remarks and Next Steps** Speaker: **Samuel Caughron**, MD
3:30 pm	**Depart**

Biographies

Program Chair

Samuel K. Caughron, MD, is the current Chair of AMP's Economic Affairs Committee, and a member of AMP's Professional Relations Committee and Board of Directors. Before becoming Chair, Dr. Caughron served on the Economic Affairs Committee as co-chair from 2010-2014, as well as serving on the Nominating Committee from 2012-2014.

In addition to his service to AMP, Dr. Caughron has served on professional pathology and medical committees for the College of American Pathologists, Association of Community Cancer Centers, Missouri Society of Pathology, the Catholic Medical Association Guild-Kansas City, American Pathology Foundation, the Kansas Medicare Carrier Advisory Committee, and the Medicare Evidence Development & Coverage Advisory Committee.

Dr. Caughron is the Chair of Pathology and Laboratory Medical Director for Shawnee Mission Medical Center. Since 2009, Dr. Caughron has also served as the President and CEO of the MAWD Pathology Group and the Founding Director of the MAWD Molecular Laboratory in Kansas City, Missouri. He is Board Certified in Anatomic and Clinical Pathology and Molecular Pathology. Dr. Caughron received his medical degree and did his Anatomic and Clinical Pathology residency at Creighton University Medical Center in Omaha, Nebraska. He completed his Molecular Genetic Pathology fellowship at Vanderbilt University. After his fellowship, he established and directed a molecular genetic pathology laboratory in Billings, Montana.

Program Facilitator

Amy M. Miller, PhD, is the President and Chief Executive Officer of the Society for Women's Health Research (SWHR), a nearly 30-year-old nonprofit dedicated to eliminating imbalances in health care for women through science, policy, and education.

Dr. Miller previously worked at the Personalized Medicine Coalition (PMC), where she served as Executive Vice President, working with innovators, scientists, providers, and payers on scientific policy and business challenges impacting personalized medicine.

Before joining PMC, Dr. Miller worked in the office of the Director of the National Institute of Mental Health, where she served as a liaison among the scientific community, the legislative branch, and the consumers of mental health care and their families.

A former American Association for the Advancement of Science Fellow, Dr. Miller also served as a domestic policy advisor to Senator Jay Rockefeller. She began her career as a researcher at the National Institute of Child Health and Human Development (NICHD).

Dr. Miller received a bachelor's degree from the University of New Orleans and holds a doctoral degree in human development from the University of Connecticut.

Planning Committee Members

Pranil Chandra, DO is a member of the American Society of Clinical Pathology, College of American Pathologists, and Association of Molecular Pathology (AMP). Dr. Chandra is currently the Vice-Chair of Coverage Decisions for the Economic Affairs Committee. In this role, Dr. Chandra provides leadership to AMP's response on any matters related to coverage of molecular pathology testing.

Dr. Chandra serves as Chief Medical Officer and Vice President of Genomic and Clinical Pathology Services at PathGroup, which is one of largest privately-owned pathology groups in the United States today. Dr. Chandra holds board certifications in anatomic and clinical pathology, hematopathology and molecular genetic pathology. He completed his AP/CP training and fellowships in hematopathology at NYU Langone Medical Center. This was followed by oncologic pathology and molecular pathology fellowships at the University of Texas-MD Anderson Cancer Center, where he served as Chief Fellow

Jennifer Dien Bard, PhD D(ABMM), is a member of the AMP's Economic Affairs Committee and AMP Annual Meeting Program Committee. She also serves on the multiple American Society for Microbiology (ASM) committees, including the Professional Development Committee and ASM Microbe planning committee. She is currently also a member of the Clinical and Laboratory Standards Institute (CLSI) Methods and Development Standardization Working Group and is on the Journal of Clinical Microbiology Editorial Board.

Dr. Dien Bard earned her PhD in Medical Sciences at the University of Alberta, Canada, followed by completion of a post-doctoral fellowship in Medical and Public Health Microbiology at UCLA. In 2012, Dr. Dien Bard took on the role of Director of Clinical Microbiology and Virology at Children's Hospital Los Angeles. She is also an Associate Professor with Clinical Scholar designation in the Department of Pathology, Keck School of Medicine, at the University of Southern California. Dr. Dien Bard is a frequent speaker on the topics of rapid molecular diagnostics and is a Consultant for many Infectious Diseases Diagnostic companies.

Susan J. Hsiao, MD, PhD is an Assistant Professor in the Department of Pathology and Cell Biology at Columbia University Medical Center. She serves as Director of Bioinformatics in the Laboratory of Personalized Genomic Medicine. Her interests include translational research in cancer genomics, improvements in storage and reporting of clinical genomics data, and utilization, coverage and reimbursement of molecular assays. She is a member of AMP's Economic Affairs Committee and the Training and Education Committee. She received her MD and PhD degrees from New York University School of Medicine. She completed residency training in anatomic pathology at New York Presbyterian Hospital/Columbia University Medical Center and completed fellowship training in molecular genetic pathology at University of Pittsburgh Medical Center.

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Anthony "Nino" Sireci, MD is the Sr. Medical Director, Medical Affairs at Loxo Oncology. Dr. Sireci is a board certified Clinical Pathologist and a practicing molecular pathologist. Prior to joining Loxo, he was an Assistant Professor of Pathology and Cell Biology at Columbia University and a medical director in the Laboratory of Personalized Genomic Medicine at Columbia Medical Center. He is an active member of the Association for Molecular Pathology (AMP) where he serves as the vice chair for new codes and pricing on the Economic Affairs Committee. He is also a member of the Pathology Coding Caucus in the College of American Pathologists (CAP) and the Molecular Pathology Advisory Group in the American Medical Association (AMA). Dr. Sireci received a B.A in chemistry from New York University and an MD from the Johns Hopkins University School of Medicine. He completed his residency training in Clinical Pathology in the New York Presbyterian Hospital-Columbia, where he also served as chief resident.

About AMP

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,500+ members include individuals from academic and community medical centers, government, and industry; including pathologist and doctoral scientist laboratory directors; basic and translational scientists; technologists; and trainees.

Through the efforts of its Board of Directors, Committees, Working Groups, and members, AMP is the primary resource for expertise, education, and collaboration in one of the fastest growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high quality, appropriate testing.

AMP Association for Molecular Pathology

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AMP Association for Molecular Pathology

AMP2019 ANNUAL MEETING & EXPO

ANNIVERSARY CELEBRATION

November 7-9, 2019
Baltimore Convention Center
Baltimore, MD

PRE-MEETING EVENTS
Guest Society Symposia,
Reference Materials Forum, &
Advocacy Hill Day
November 5

Corporate Workshop Day &
Molecular Pathology Outreach Course
November 6

AMP19.amp.org