View this as a webpage

AMPlifications™

Vol. 21, No. 4, December 2015
Printable Version

ADVOCACY

The Economic Affairs Committee sponsored a symposia at the AMP annual meeting on Coding, Coverage, and Reimbursement of Molecular Diagnostic Tests. **Aaron D. Bossler**, MD, PhD, 2015 EAC Chair, gave an overview of AMP's initiatives to communicate with payers in order to obtain adequate coverage and payment for molecular pathology procedures, including genomic sequencing procedures (GSPs). The session also included presentations from various leaders in the field including Rina Wolf, MHA, **John Pfeifer**, MD, PhD and **Erick Lin**, MD, PhD, all of whom are very knowledgeable regarding reimbursement for molecular diagnostic tests. To read more about the session please visit: http://www.amp.org/documents/AMPSymposiumonCodingCoverageReimbursement_FINAL.pdf The long overdue Medicare Clinical Diagnostic Laboratory Tests Payment System proposed rule was released on September 25, 2015, implementing the provisions of the Protecting Access to Medicare Act (PAMA). **AMP submitted comments on the proposed rule on November 24, 2015.** AMP's comments express concern about a number of issues in the proposed rule including the narrowly-defined advanced diagnostic laboratory tests (ADLTs); the data collection and reporting timeline; the gapfill process; the local coverage determination (LCD) process; and consolidation of the Medicare Administrative Contractors (MACs). Additionally, AMP's comments voiced support for a new CPT code set approved by AMA CPT editorial panel to fulfill the PAMA codification requirements and made suggestions to CMS on ways to maximize the expertise of the Advisory Panel on Clinical Diagnostic Laboratory Tests as well as suggestions to the gapfill process that would increase its transparency. AMP's comments to CMS on the proposed rule are available here: http://amp.org/publications_resources/position_statements_letters/documents/AMPCommentstoCMSonPAMA-CMS-1621-P-FINAL.pdf

CMS released the **Calendar Year 2016 Clinical Laboratory Fee Schedule (CLFS) Final Determinations.** AMP is pleased that CMS adopted most of our proposed crosswalk recommendations for the Tier1 Molecular Pathology CPT codes for CY2016. However, AMP supported crosswalks for the 2016 genomic sequencing procedure (GSP) CPT codes and is concerned that the 2016 GSP CPT codes will undergo gapfill to determine pricing. The 2015 gapfill process for GSP CPT codes resulted in low or non-existent prices for these codes and the lack of transparency involved in the gapfill process has left it unclear how each contractor determined prices and what data was utilized. To mitigate these concerns, AMP supports increased transparency in the gapfill process proposed by CMS in the Medicare Clinical Diagnostic Laboratory Tests Payment System proposed rule. The final determinations are available here: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2016-CLFS-Codes-Final-Determinations.pdf

AMP continues to advocate with CMS regarding actions taken by Medicare Administrative Contractors (MACs). **It is important that all AMP members be aware of draft LCDs, articles, and other policies in their jurisdictions that could restrict patient access to testing.** Tara Burke, AMP's Policy Analyst, distributes on CHAMP new draft LCDs regarding molecular tests. Be alert also for notices directly from your MAC. **Communicate your concerns directly to your MAC Medical Director**, contact information may be found at: https://www.cms.gov/medicare-coverage-database/indexes/contacts-part-b-medicare-administrative-contractor-index.aspx?bc=AgAAAAAAAAAA&

Next Generation Sequencing (NGS) Reimbursement: AMP officially released the micro-cost and health economic models in March 2015 with **over 450 downloads** thus far. We hope members are utilizing these models to accurately calculate the cost of their NGS services and, therefore, effectively communicate value and cost to payers. AMP is currently conducting a survey. It is important that all who download the models complete this survey so we can determine use of the models and outcomes. The models and supporting materials are available here: http://amp.org/committees/economics/NGSPricingProject.cfm

Annual Meeting Session on Modernization of CLIA Regulations for Laboratory Developed Testing Procedures. The session, sponsored by the Professional Relations Committee, featured keynote speaker Congressman Michael Burgess, MD (R-TX), a member of the House Energy & Commerce Committee, who introduced legislation in 2011 to update the current CLIA regulations and is a long-time supporter of modernizing and strengthening the existing CLIA program. **Roger Klein**, MD, JD, gave an overview of AMP's proposal followed by a panel consisting of representatives from various types of laboratories including a reference laboratory (Marc Grodman, MD, BioReference Laboratories) , an academic laboratory (**Cindy Vnencak-Jones**, PhD, Vanderbilt University Medical Center) , and a community medical center (**Karen Kaul** MD, PhD, Northshore University Health System). For a recap of the session please read the press release on this session, available online at: http://amp.org/documents/FINALAMPCLIAModernizationSessionatAnnualMeeting2015.pdf Panelists urged attendees to take action and communicate support of AMP's CLIA Modernization Proposal to key members of Congress. For more information, please visit http://www.amp.org/advocacy/CLIAModernization.cfm

The House Energy and Commerce Subcommittee on Health held a hearing on the regulation of laboratory developed procedures (LDPs), also known as laboratory developed tests (LDTs), on November 17, 2015. The hearing was used to contrast the draft legislation released by the Committee with the FDA's proposed framework for regulating LDPs that was issued last year in a draft guidance. Committee leadership on both sides of the aisle expressed support for creating a new pathway forward using legislation but were divided over whether expanded regulation from FDA is a good idea. The hearing also gave FDA and CMS officials an opportunity to clarify their current role in regulating LDPs and, in addition, their capacity for expanding their roles in the future. You can view the hearing and read the testimonies of Drs. Jeffrey Shuren (FDA) and Patrick Conway (CMS) at http://energycommerce.house.gov/hearing/%E2%80%9Cexamining-regulation-diagnostic-tests-and-laboratory-operations. In brief, Dr. Conway testified that it is impossible for CMS to review clinical validity due to its small staff and lack of appropriate expertise. Both agencies testified that they believe the best division of oversight is for FDA to conduct pre-market reviews of LDPs and CMS to continue to conduct post-market activities. **Rep. Collins (R-NY) entered the testimony of Jan Nowak, MD, PhD into the record and Rep. Burgess (R-TX) submitted AMP written testimony into the record. AMP's testimony is available here:**http://amp.org/publications_resources/position_statements_letters/documents/AMPEChearingtestimony-11-16-2015-final.pdf

EDUCATION

Congratulations to the **2015 International Trainee Travel Award winner**:
Manjistha Ahooja, Tata Memorial Center, Mumbai, India

Congratulations to the **2015 Technologist Travel Award winners**:
Mark J. Bowser, MS, MPH, Massachusetts General Hospital/Harvard Medical
Rebecca Stolarczyk, BS, UMass Memorial Medical Center
Yigin Xiong, MD, PhD, UMass Memorial Medical Center

Congratulations to the **2015 Technologist Poster Award winners**:
Mary Beth Durso, MS, University of Pittsburgh Medical Center. ST04: *Development of Clinical Transcriptome (RNA-Seq) Analysis for Detection of Fusions and Gene Expression in Oncology Samples*
Stephanie Puetz, MS, Medical College of Wisconsin, Milwaukee. ST24: *Myxoinflammatory Fibroblastic Sarcoma: Association of t(1;10) Translocations in a Cohort of 49 Cases by Fluorescence in Situ Hybridization*
Mustafa Syed, MS, Memorial Sloan Kettering Cancer Center, New York. I32: *MSK-LYMPHOCLONE: Data Analysis Pipeline and Tools for Immune Repertoire Analysis*

Congratulations to the **2015 Young Investigator Award winners**:
Midhat Farooqi, MD, PhD, UT Southwestern Medical Center, Dallas. I44: *Multi-Institutional FASTQ Proficiency Testing Reveals High Concordance in Reporting Clinically Significant Single-Nucleotide Variants but Discrepancies in Reporting Insertions/Deletions*
Gloria Haskell, PhD, University of North Carolina, Chapel Hill. G18: *Clarifying Diagnoses: Application of Exome Sequencing for Neuromuscular Disorders.*
Jacquelyn Reuther, PhD, Baylor College of Medicine, Houston. ST02: *Diagnostic Yield and Utility of RNA Sequencing in the Detection of Pathogenic Fusions in Childhood Sarcomas of Uncertain Diagnoses*
Yening Daniel Xia, MD, Beth Israel Deaconess Medical Center, Boston. H30: *Systematic Analysis of Common Copy Number Variations in Diffuse Large B-cell Lymphomas*

AMP's educational collaborations continue with other organizations such as:
Online Monthly (free!): **ASCO/CAP/AMP Molecular Oncology Tumor Board Case Study Series**. Go to https://connection.asco.org/discussion/lung-december-2015-molecular-oncology-tumor-boards to review December's case study and post your comments on the discussion board. Previous months' case study topics included Prostate cancer, Acute Myeloid Leukemia, and Thyroid cancer.

Molecular Medicine Tri-Conference 2016 (March 6-11 in San Francisco).
March 6: "NGS Assay Selection, Validation and Compliance" short course presented by **Eric Duncavage**, **Colin Pritchard**, and **Avni Santani**.

USCAP 2016 (March 12-18 in Seattle).
March 13: AMP Companion Meeting symposium, "Implementing Molecular Testing to Make Treatment Decisions", with presentations by **Eric Duncavage**, **James Cook**, **Jeffrey Klco**, **Christina Lockwood**, and **David Wu**.
March 14: Trainee Breakfast Reception.
March 15: Co-branded Molecular Course presented by AMP members **Iris Schrijver** and **George Netto**.

For an up-to-date listing of AMP at associated meetings, visit: http://www.amp.org/meetings/associated/index.cfm

Registration is opening soon for the T&E Committee's January webinar on the topic of Clonal Hematopoiesis of Indeterminate Potential (CHIP), to be presented by Dr. Benjamin Ebert.

Trainee Volunteers Wanted: Applications for serving the Training & Education Committee as a junior member will be accepted soon. Watch for the upcoming announcement on CHAMP and the Trainee community listserv.

INNOVATION & IMPROVED PATIENT CARE

AMP hosted the annual **Reference Material Forum** on Tuesday November 3 in Austin, Texas, This open forum event was organized by **Lisa Kalman** prior to the AMP 2015 Annual Meeting and was very well attended. Thank you Lisa for your hard work and to all the presenters for a great program!

The **Clinical Practice Committee** of AMP hosted two Specialty Lunch sessions and two workshops at the AMP 2015 Annual Meeting. The sessions were very popular and the slides will be available to registered meeting attendees shortly. The speakers thank the attendees for their valuable feedback.

AMP launched the Developing Standards for Next-generation Sequencing (NGS) Bioinformatics Pipeline Validation: Single Nucleotide Variants (SNVs), Small Indels (<=21bp) and Multi-nucleotide Variants (MNVs) Working Group. **Somak Roy** was appointed Chair and **Alexis Carter**, **Annette Meredith**, **Christopher Coldren**, **Eric Klee**, **Nefize Sertac Kip** and **Arivarasan Karunamurthy** were appointed to the project workgroup.

The **CNV Working Group launched a survey** to gather information from laboratories offering clinical tests to establish best practices and develop guidelines for laboratory detection and interpretation of intragenic (exonic level) deletions/duplications. Survey closed on November 23, 2015.

The **CPC will be recruiting for a 2016 Junior Member** – application at http://amp.org/Get_Involved/volunteer_at_AMP.cfm to open soon!
See http://amp.org/about/elected_positions-descriptions.cfm#CP for more information regarding the position.

FDA held two back-to-back workshops on November 12 and 13, each focusing on two different aspects of Next Generation Sequencing In Vitro Diagnostic Tests. The workshop on November 12 discussed a standards-based approach to analytical performance evaluation of NGS in vitro diagnostic tests and the topic of the November 13 workshop was the use of databases for establishing the clinical relevance of human genetic variants. The purpose of the workshops was to hear from the stakeholder community about the current approaches and optimal design of both analytical performance standards and the use of databases for NGS in a clinical setting. AMP provided oral comments at both workshops and also summited written comments. The written comments are available here:
http://amp.org/publications_resources/position_statements_letters/documents/AMPCommentsonAnalyticalStandardsforNGS-FDA-2015-N-2881-FINAL.pdf
http://amp.org/publications_resources/position_statements_letters/documents/AMPCommentsonUseofDatabases-FDA-2015-N-3015-FINAL.pdf

Marina Nikiforova, Chair of the Clinical Practice Committee (CPC) would like to thank all departing CPC and Subdivision leadership for their service during the past year.

2016 CPC and Subdivision leadership members have now assumed their role and responsibilities. Please visit AMP's Clinical Practice Committee http://amp.org/committees/clinical_practice/members.cfm or Subdivision Leadership http://amp.org/subdivisions/index.cfm webpages to identify these leaders and for more information on AMP initiatives.

9650 Rockville Pike, Bethesda, MD 20814-3993 (USA)
Tel: 301-634-7939 | Fax: 301-634-7990 | Email: amp@amp.org | www.amp.org | @AMPath