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# AMPlifications™

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## ADVOCACY



### Molecular pathology CPT codes; payment and coverage

During the public meeting for the new Clinical Laboratory Fee Schedule (CLFS) services on July 14, AMP was represented by **Aaron Bossler** and **Roger Klein** who commented regarding pricing for the new Gene Sequencing Assay (GSA aka NGS) CPT codes and CLFS reform provision in the Protecting Access to Medicare Act (PAMA) bill, respectively. The new CPT book will be released in September.

Representatives from the AMP EAC met with Tamara Syrek-Jensen, Director, CMS Coverage and Analysis Group, this month to discuss Medicare Coverage of molecular services and AMP's concerns with the expansion of the Palmetto MolDx program, PAMA implementation, and retroactive payments for CPT Tier 1 and 2 codes.

**AMP responded to several new dLCDs issued by NGS, CGS, and First Coast and expects to respond to ones from Cahaba and Noridian as well.** In addition to commenting on dLCDs and engaging directly with CMS, staff of our coalition organizations are meeting to discuss possible strategies regarding the expansion of MolDx. It is complex and now includes FDA oversight of LDTs and PAMA.

**AMP submitted comments on the proposed 2015 Physician Fee Schedule.** Those comments can be accessed via this link: <http://bit.ly/1pHKdy>

On July 24, a Call to Action was sent to AMP members requesting participation in an important AMP project: **Micro-costing and Health Economic Value Analysis of Genomic Sequencing Procedures (GSPs)**. Thank you to those that responded! Boston Healthcare Associates is collecting and will analyze information about laboratory workflow and professional interpretation to support documentation of the full cost of performing key GSP assays (specifically Whole Exome, targeted solid organ neoplasms, and panels such as X-linked intellectual disability or Hearing Loss). Information will also be collected to demonstrate the value of next generation sequencing assays, which will be critical to establishing a favorable reimbursement and market access environment. If you would like to participate or have questions, please contact AMP NGS Pricing Project Manager **Katherine Tynan** ([Katherine.tynan@tynandx.com](mailto:Katherine.tynan@tynandx.com)).

### NGS CPT Code Proposal

AMP will be submitting CPT code change proposals in November for 2016 publication.

### Overview of LDTs and Companion Diagnostics

In early July, five Senators sent a letter to the Office of Management and Budget (OMB) in the White House pressing them to publish the draft guidance documents establishing a framework to regulate LDTs. AMP has subsequently met with those offices to discuss this policy issue. Specifically, AMP met with Senators Durbin (D-IL), Brown (D-OH), Warren (D-MA), and Markey (D-MA). In the visits, AMP confirmed that they do not have a position on the FDA regulation of LDTs, but rather, they are concerned about the delay in the OMB finalizing regulations and cited the LDT guidance documents as an example. AMP will continue to engage Congress on this important issue.

On July 31, 2014, the FDA notified Congress that in at least 60 days they intend to publish a draft guidance document entitled **Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)** (Framework Guidance) and an accompanying draft guidance document entitled **FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)**. The notice and details of the guidance document can be found here: <http://1.usa.gov/1pHKQsg>. AMP is analyzing the proposed policy and intends to continue meeting with Hill offices and also the FDA to express its concerns.

The AMP Professional Relations Committee will host a webinar titled **"FDA Laboratory Developed Test (LDT) Draft Guidance and the Potential Impact on Clinical Practice,"** presented by **Roger Klein** and Jennifer Leib on Tuesday, September 16 at 1:00pm (Eastern). Register online now at <https://www2.gotomeeting.com/register/944840810>

### White Papers

Separate whitepapers addressing threats to the field of molecular pathology and clinical utility, respectively, are in process.

### Capitol Hill

**Frank Cockerill** participated in the 21st Century Cures Roundtable on Personalized Medicine on July 23, in which he noted AMP by name, the critical need for appropriate payment, and indicated that PhDs should be recognized as Qualified Healthcare Professionals.

Over 70 AMP members are expected to participate in **AMP Advocacy Day** on November 12, 2014! We aim to educate Congressional offices on the following themes:

1. The value of molecular testing and the critical role of the molecular professional to positively impact patient care.
2. The potential impact of the FDA draft guidance on oversight of LDTs.
3. The potential impact of the "Protecting Access to Medicare Act of 2014" (PAMA).

## AMP AT WORK FOR YOU



There's still time to volunteer to serve as a member of the AMP Membership Affairs Committee. **Applications are due by September 15, 2014** at 11:59 PM EST. Notification of appointments will be made in early October. **All members are encouraged to apply, particularly those with an interest in infectious diseases or informatics.** Apply online at: <http://bit.ly/1CKpKDK>.

Applications are being accepted for free registration for the **AMP Online Molecular Genetic Pathology Review Course**. This opportunity is for members outside the U.S. Preference will be given to those in low income countries per the World Bank Classifications. Eligible members may apply online at: <http://bit.ly/1okBy69>. The deadline to apply is September 10.

The Membership Affairs Committee and the International Affairs Working Group look forward to hosting a number of **special events during this year's Annual Meeting**. All of these events take place on Thursday, November 12:

1. "Caffeinate Your Career" Early Bird Session, hosted by the MAC
  2. New Members & First Time Attendees Luncheon, hosted by the MAC
  3. Global Molecular Pathology Network Luncheon, hosted by the IAWG
- Details about these and other special events to be held during the AMP 2014 Annual Meeting are online at: <http://www.amp.org/meetings/2014/specialevents.cfm>

## EDUCATION



The **AMP 2014 Molecular Pathology Outreach Course**, AMPlicons: A Practical Molecular Toolkit and Case Studies, will be offered on Wednesday, November 12 at the Gaylord National Resort & Convention Center at the National Harbor, MD (just outside of Washington, DC). Pathologists, residents, laboratory directors and technologists who have little experience with molecular diagnostic testing are encouraged to attend. The course will provide an overview of techniques and instrumentation used in molecular testing from the framework of the "Molecular Pathology/Molecular Diagnostic Toolkit." Space is limited, so register today at: [www.amp.org/mpoc](http://www.amp.org/mpoc). This course is supported by Illumina and co-sponsored by The College of American Pathologists, the Maryland Society of Pathologists, and the Virginia Society for Pathology.

Coming later this month: Be on the look-out for the Training & Education Committee's annual **Educational Needs Survey!** Provide feedback and commentary to help identify what knowledge gaps in molecular diagnostics and genomics should be addressed in 2015. Results of this online survey will be presented at a special working luncheon session at the AMP 2014 Annual Meeting.

### Textbook Donations for AMP Trainee Luncheon Drawing

Are you a textbook author and/or editor? Consider donating one or two textbooks for the annual trainee textbook drawing at the AMP 2014 Annual Meeting. In the past, donors have included a business card or a personal message in the textbook for the trainee recipient. Please feel free to do the same, or you may remain anonymous. AMP can provide a tax deductible receipt for your contribution upon request. Please have the books shipped to arrive on or before **Monday, October 20** at: Association for Molecular Pathology, Attn: Trainee Textbook Drawing, 9650 Rockville Pike, Bethesda, MD 20814 (USA).

The Training & Education Committee launched a **new series of five webinars** on the basics of next generation sequencing this July. The inaugural lecture was "NGS 101 for the Clinic" presented by **Birgit Funke**. The webinar was recorded and now archived in the member-only AMP Web Library. The upcoming "NGS101" webinar topics scheduled to date this fall are:

**"Viewing and Interpreting Sequencing Data: An Introduction to Genome Browsers,"** presented by **Patrik Vitazka** on Thursday, September 11 at 1:00pm (Eastern). Register online now at: <https://www2.gotomeeting.com/register/450176490>

**"Nomenclature in the Context of NGS,"** presented by **Robert Daber** in late September/early October.

In addition, the T&E will host the following webinar:

**"Molecular Diagnostics for Global Health,"** presented by Ellen Jo Baron on Tuesday, September 23 at 1:00pm (Eastern)

"Live" AMP Webinars are free to all registrants: [http://www.amp.org/Webinars/future\\_webinars.cfm](http://www.amp.org/Webinars/future_webinars.cfm)

Congratulations to **Giovanni Insuasti** who has been appointed as the AMP representative to ASCP's Resident In-Service Examination Committee for 2014-2015!

AMP continues to collaborate with other organizations by providing endorsement and/or AMP member expertise to present educational sessions in molecular diagnostics, including:

- CAP '14 on September 7 in Chicago, IL, a plenary session on "Molecular Medicine - Can We Afford It?" that discusses the economics of diagnostics, co-organized with **Jordan Laser** for AMP: <http://thepathologistsmeeting.org/scientific-plenary.html>
- The Beaumont Annual Symposium on Molecular Pathology in Troy, MI, on September 16-17 with sessions presented by **Jennifer Hunt, Laura Tafe, and Glenn Palomaki**. <http://www.beaumontlaboratory.com/dnasymposium>
- ASCP 2014 on October 8 in Tampa, FL, a "Molecular Diagnostics Primer" course taught by **Jane Gibson** and developed by **Giovanni Insuasti** and **Ted Schutzbank**. <https://www.ascp.org/services/annualmeeting/sessionfinder?productID=43856206>

## INNOVATION & IMPROVED PATIENT CARE



AMP continues to work collaboratively with other organizations to improve clinical practice and patient care:

**Alexis Carter** was appointed AMP liaison to the **CDC's Lab Messaging Community of Practice (LabMCoP)** work group. For more information visit <http://www.phconnect.org/group/laboratorymessagingcommunityofpractice>.

**Monica Basehore** represented AMP at the National Institute of Standards and Technology (NIST) **Genome in a Bottle Consortium Workshop Steering Committee** August 14-15, 2014. For more information about this project visit <http://genomeinabottle.org/>. In April 2014, the WGA Working Group conducted a survey that provided NIST GIAB feedback on reference materials from both AMP members and internationally. To view the results visit [http://www.amp.org/committees/clinical\\_practice/cpwg\\_gen\\_fm](http://www.amp.org/committees/clinical_practice/cpwg_gen_fm).

**Andrea Ferreira-Gonzalez** is presenting on behalf of AMP at the Sept. 24-25, 2014 **FDA Public Workshop: Next Generation Sequencing Standards Workshop**. This public workshop on NGS technology, data format standardization and promotion of interoperability protocols aims to facilitate establishing protocols for ensuring the safety and quality of NGS-related information without sacrificing scientific merit or interfering with innovative processes. In addition, it will highlight FDA-proposed guidelines for addressing NGS data storage, archival and quality control steps needed for computational biology protocols related to FDA relevant regulatory science. The on-site conference capacity is currently full, but you may still be able to register for the webcast at <http://www.eventbrite.com/e/next-generation-sequencing-ngs-technology-data-formats-standardization-and-promotion-of-tickets-10927776273>.

AMP is a member of the **FDA's Network of Experts** – watch CHAMP announcements for upcoming opportunities to volunteer!

AMP is hosting a **Reference Material Forum** being organized by **Lisa Kalman** on Tuesday November, 11 from 8:30 am – 4:30 PM at the Gaylord National Resort & Convention Center. There is no registration fee for this open forum meeting prior to the AMP 2014 Annual Meeting, but space is limited. If you would like to attend, please send an email to [LKalman@cdc.gov](mailto:LKalman@cdc.gov). A final agenda will be posted by November at: <http://www.amp.org/meetings/2014/specialevents.cfm>

Members of the **ASCP/CAP/AMP Clinical Practice Guidelines Development Group for the Evaluation of Molecular Markers for Colorectal Cancer** will be presenting the status of their work at the AMP 2014 Annual Meeting on Saturday, November 15 from 10:45am - 12:15pm. The representatives for AMP are **Antonia Sepulveda** (Co-Chair), **Federico Monzon, Noralane Lindor**, and **William Funkhouser**.

The AMP Publications and Communications Committee continues to invite **case report articles** for possible submission to CAP TODAY. View prior articles, take the self tests, and read about submitting a report online at:  
[http://www.amp.org/publications\\_resources/AMPCaseReviews.cfm](http://www.amp.org/publications_resources/AMPCaseReviews.cfm)

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