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ADVOCACY



Next Generation Sequencing (NGS) Reimbursement: In 2014, CMS announced that it will gap-fill all of the new Genomic Sequencing Procedure (GSP) CPT codes. During 2015, labs will need to work with MACs and commercial payers to ensure adequate values for these codes. To help estimate the cost basis of their GSP services, AMP initiated a micro-costing and health economic evaluation of several of these CPT codes. These models will help laboratories accurately calculate the cost of their NGS services and, therefore, effectively communicate value and cost to payers. AMP recently held a webinar on these cost and health economic models and **officially released the models in March 2015**. Hampering the success of pricing efforts is emerging non-coverage decisions for multi-gene sequencing assays, so this will be a major advocacy focus in 2015. The models and supporting materials are available here: <http://amp.org/committees/economics/NGSPricingProject.cfm>

Medicare Administrative Contractors: AMP continues to respond to problematic draft LCDs. In March, joint AMP/CAP responses were sent to Noridian, Novitas, and Palmetto. AMP continues to advocate regarding the Palmetto MoIDX coverage and payment policies, which are influencing coverage policies in other Medicare jurisdictions as well as private payers.

NGS CPT Code Proposals: AMP submitted CPT code change proposals in November for 2016 publication. A number of them were accepted including Hereditary Neuroendocrine Disorders, Noonan Spectrum Disorders, Hereditary Colorectal Cancer Panel Edit, Hereditary Breast Cancer-Related Syndrome Panel and Ashkenazi Carrier Panel.

Proposals for Oversight of Laboratory-Developed Procedures (LDPs): AMP submitted written comments to FDA on its draft guidance; available here: <http://www.amp.org/advocacy/documents/FDAcommentsonLDTguidance-FINAL.pdf>. AMP leadership has been briefed on a proposal ("DTWG") promoted on Capitol Hill by a group of product manufacturers and commercial reference laboratories. Both the House Energy & Commerce and Senate HELP Committees have indicated that they may include legislation regarding oversight of LDPs in larger bills this year and the group hopes its proposal will form the backbone. AMP has been active in meetings with E&C and HELP staff and has provided an analysis regarding how each regulatory proposal measures up to AMP's principles for oversight of LDPs.

Oversight of NGS: AMP formed a workgroup for the purpose of formulating comments to FDA on its white paper titled "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests". Roger Klein presented verbal comments on February 20, 2015. The workgroup submitted written comments on March 20, 2015. The comments are available here: http://amp.org/documents/AMPNGSWrittenComments_final_March2015.pdf

In January and February 2015, AMP responded to questions posed by the House Energy & Commerce Committee regarding LDPs and the Medicare Local Coverage Determination process. These documents are available here: http://amp.org/publications_resources/position_statements_letters/documents/AMPrespondetoECRFFinal.pdf
http://amp.org/publications_resources/position_statements_letters/documents/AMPlettertoEConCuresAct-FINAL.pdf

In February 2015, AMP provided feedback to the Senate Committee on Health, Education, Labor and Pensions on the report "Innovation for Healthier Americans" regarding LDPs and challenges facing coverage and reimbursement. The comments are available here: http://amp.org/publications_resources/position_statements_letters/documents/AMPrespondetoSenatereport-FINAL.pdf

New Position Statement on DTC: AMP released a new position statement on Direct Access Genetic testing. The position states that clinically meaningful tests could benefit patients and consumers and should be available to the public, but only if certain conditions are met. The position statement is available here: http://amp.org/publications_resources/position_statements_letters/documents/AMPPositionStatementDTCtesting-FINAL_002.pdf

In January, AMP released a white paper titled **A Molecular Diagnostic Perfect Storm: The Convergence of Regulatory & Reimbursement Forces that Threaten Patient Access to Innovations in Genomic Medicine** detailing these challenges and utilizes it to support advocacy initiatives. This paper is the result of a collaboration between members from the Clinical Practice, Economic Affairs and Professional Relations Committees. The white paper is available here: (http://amp.org/publications_resources/position_statements_letters/documents/PerfectStorm-FINAL-CD.pdf)

Advocacy Day Recap: At the annual meeting, over 50 members visited Capitol Hill offices. Drs. Janina Longtine, Elaine Lyon, Roger Klein, and Aaron Bossler provided a lunchtime briefing for congressional staff. During their meetings with legislative staff, AMP members emphasized the essential role of the molecular pathology professional and molecular testing to patient care. In addition, requests regarding FDA oversight of LDPs and coverage and payment issues were presented. Planned 2015 advocacy activities will advance AMP's positions in these areas.

In conjunction with Advocacy Day, AMP launched its grassroots system. This online system allows AMP members to easily contact elected federal officials and ask them to act on specific AMP-related issues. Hundreds of AMP members participated in the first outreach. Congressional staff has been very responsive. Constituent contacts definitely get their attention! Visit www.amp.org/congress for details.

AMP AT WORK FOR YOU



Your input matters! Help AMP to better serve you by completing the Member Survey online at <https://www.surveymonkey.com/s/GW88VH8>. The deadline is April 30! Take 1-2 minutes today to provide your input.

EDUCATION



The AMP Molecular Genetic Pathology Review Course will take place April 30 - May 3, 2015 DoubleTree by Hilton Hotel Bethesda - Washington DC. Course objectives are to assist attendees' preparation for the MGP Subspecialty Certification Exam (offered jointly by the American Board of Pathology and the American Board of Medical Genetics), as well as other certification exams in molecular pathology and molecular genetics and increase basic and applied pathology knowledge, focusing on the molecular pathogenesis, diagnosis, prognosis and treatment of disease. Eligible members may apply online at: <http://www.amp.org/mgp2015/registration.cfm>

The abstract submission system is now open! Submit your abstract for presentation at the 2015 Annual Meeting before the June 1st deadline. Access the system by visiting: <http://www.amp.org/meetings/2015/abstracts.cfm>

The T&E Committee is presenting a series of **Informatics 101 webinars**, including such topics as:

- o Introduction to Bioinformatics for NGS Analysis
- o Programming and Developing Standards and Quality Metrics
- o Informatics Pipelines
- o Viewing Data
- o Applications for Clinicians and Research Models
- o Reporting Data
- o Clinical Informatics

For a list of upcoming webinars and open registrations, visit: http://www.amp.org/Webinars/future_webinars.cfm. As always, these webinars are presented free of charge and are available to AMP members on-demand via the Web Library.

AMP, in collaboration with ASCO and CAP, is offering a free online monthly **Molecular Oncology Tumor Board case study series**. Michelle Schiller and Maria Arcila represent AMP on the series' planning group. Go to <http://university.asco.org/motb> to review the case study of the month and post your comments on the discussion board.

Other educational resources, including TRIG Instructor Materials, have been updated here: <http://www.amp.org/education/resources.cfm>. Note the updated Molecular Pathology Book List for 2015 linked at: http://amp.org/education/documents/MolecularPathologyBookList_Feb2015.pdf

AMP continues to collaborate with other organizations by providing endorsement and/or AMP members to present educational sessions or courses in molecular diagnostics, including USCAP, ASCP, CAP, the Beaumont Annual Symposium on Molecular Pathology, the 2015 Korean Society of Genetic & Molecular Diagnostics Annual meeting, the 2nd International Symposium on Personalized Medicine, and CHI's Clinical Genome Biomarker Conference and the Next Generation Diagnostics Summit. For an up-to-date listing, visit: <http://www.amp.org/meetings/associated/index.cfm>

A new **Technologist Member Interest Group listserv now lives in CHAMP!** Self-subscribe to this member interest group listserv by:

1. At the top of the AMP home page (<http://www.amp.org>), near the right corner, click on the "Go To CHAMP" link (<http://champ.amp.org>).
2. After logging into CHAMP, under "Quick Links" on the right-hand side, click on "My Subscriptions"
3. Then click on the "Add Subscription" button above the gray rectangle.
4. In the pop-up window, for "Select a Category" in the drop-down menu select "Member Interest Group".
5. Next in the "Select Topic" drop-down menu select "Technologist Interest Group Discussion"
6. The default "Select Subscription Type" is "Immediate Email," which sends discussion messages as soon as they are posted. You may change this by selecting another option in the drop-down menu.
7. Finally, in the pop-up window, click on the "Add" button. The Technologist Interest Group Discussion will now appear in your Forum Subscription list.

INNOVATION & IMPROVED PATIENT CARE



AMP, CAP and the International Association for the Study of Lung Cancer (IASLC) have joined forces again to update the 2013 Molecular Testing Guideline for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors project http://amp.org/committees/clinical_practice/LungBiomarkerGuideline.cfm. The Expert Panel met in March 2015 with AMP representatives Neal Lindeman (Co-chair), Dara Aisner, Lynette Sholl, Maria Arcila, and David Kwiatkowski in attendance.

Standards and Guidelines for the Interpretation of Sequence Variants: A Joint Consensus Recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology <https://www.acmg.net/docs/StandardsGuidelinesfortheInterpretationofSequenceVariants.pdf> has been published in Genetics in Medicine. Elaine Lyon and Julie Gastier-Foster were the AMP liaisons to this project.

Marilyn Li (Chair), Eric Duncavage (Co-chair), Cindy Vnencak-Jones and Somak Roy have been appointed to the AMP Interpretation of Sequence Variants (ISV) in Somatic Conditions (Cancer) Working Group. This newly formed working group will collaboratively develop consensus recommendations for ISV, building on the work described above in inherited disorders. To provide foundational information for this project, two AMP member surveys to gather information on technical and reporting aspects of Next Generation Sequencing (NGS) are currently available. Please visit <https://www.surveymonkey.com/s/99WB292> and <https://www.surveymonkey.com/s/6SBFSCQ> to add your voice!



Do you know an individual in the field of molecular pathology deserving of AMP recognition? **Please submit your nominee(s) for AMP's Award for Excellence in Molecular Diagnostics, the Jeffrey A. Kant Leadership Award and/or the Meritorious Service Award no later than Monday April 27, 2015** by completing the form at <http://goo.gl/forms/abCJcfCLQo>.

AMP elections take place during the month of May! If you are a Regular member, you will receive an email in early May from Association Voting with instructions regarding how to cast your vote. Many new well-qualified candidates are on the ballot again this year. Read the candidate statements and then "voice your choice!"

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

The Journal of Molecular Diagnostics has published **Reporting Incidental Findings in Genomic Scale Clinical Sequencing – A Clinical Laboratory Perspective** (<http://jmd.amjpathol.org/article/S1525-1578%2814%2900245-1/fulltext>), a manuscript developed by the AMP Incidental Findings Working Group, a joint working group of the AMP Clinical Practice Committee and the Whole Genome Analysis Working Group. The project was led by **Madhuri Hegde** and manuscript authored by **Sherri Bale, Pinar Bayrak-Toydemir, Jane Gibson, Linda Jo Bone Jeng, Loren Joseph, Jordan Laser, Ira Lubin, Christine Miller, Lainie Ross, Paul Rothberg, Alice Tanner, Patrik Vitazka, and Rong Mao.**

New Clinical Practice Committee (CPC) Members: The CPC has extended an enthusiastic welcome to **Somak Roy** and **Christopher Coldren** as the new Informatics Subdivision representatives and to **Arivarasan Karunamurthy** as a Junior Member.

In another AMP first, **Informatics will be holding a virtual Town Hall Meeting on April 29, 2015 at 1:00 PM Eastern time** hosted by Chair, **Alexis Carter**. Registration is now open to all AMP Informatics Subdivision members at <https://attendee.gotowebinar.com/register/1314238917447496961>. To join the Informatics Subdivision, login to your account at <https://secure.amp.org/login.cfm> and edit your subdivision selections. Email us at amp@amp.org for assistance.

Monica Basehore represented **AMP at the NIST Genome In A Bottle workshop and steering committee meeting** in Stanford, CA January 2015.

The Clinical Practice Committee and all AMP Subdivision Leadership groups kick-started the New Year with their first quarter meetings for 2015. Please contact any of AMP's Subdivision Leadership <http://amp.org/subdivisions/index.cfm> or Clinical Practice Committee http://amp.org/committees/clinical_practice/members.cfm representatives with your ideas for new AMP initiatives!

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9650 Rockville Pike, Bethesda, MD 20814-3993 (USA)

Tel: 301-634-7939 | Fax: 301-634-7990 | Email: amp@amp.org | www.amp.org | [@AMPPath](https://twitter.com/AMPPath)