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AMPlifications™

Vol. 19, No. 4, September 2013

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ADVOCACY



Reimbursement for molecular pathology tests is AMP's primary advocacy issue!

View all of AMP's position statements and comments online at: http://www.amp.org/publications_resources/position_statements_letters/2013AMPPositionStatements.cfm

• **Gapfill Pricing:** AMP submitted comments to CMS to explain its concerns about the gapfill process for pricing the new codes and to recommend modifications to the preliminary gapfill process part of the official public record regarding the 2013 gapfill payment amounts. CMS is slated to report their final determinations in September. During the 2013 Clinical Laboratory Fee Public Meeting on July 10, **Katherine Tynan** presented **AMP's crosswalk recommendations** for new codes 81161, 812XX, and 876XX. Additionally, AMP is working with a coalition of other professional associations and as a member of the **Coalition to Strengthen the Future of Molecular Diagnostics (CSFMD)**.

• **Coverage Issues:** Comments were submitted in response to the following Medicare Administrative Contractor (MAC) Draft Local Coverage Determinations (LCD):
WPS - Molecular Diagnostic Testing (PATH-037) (DL33219)
Novitas - Biomarkers Overview (DL33640 and DL33638)
First Coast - Molecular Pathology Procedures for Human Leukocyte Antigen (HLA) Typing (DL33732)
First Coast - Molecular Pathology Procedures (DL33703)
Palmetto - Genetic Testing for Lynch Syndrome (DL33779)
Palmetto - Molecular Diagnostic Tests (MDT) (DL33599)
 If you would like to **view the letters**, please visit: http://www.amp.org/publications_resources/position_statements_letters/2013AMPPositionStatements.cfm

• **Many thanks to those who helped to prepare the letters or agreed to be the contacts** for the local MAC comments including Kay Jewell, **Aaron Bossler**, **Jan Nowak**, **Katherine Tynan**, **Roger Klein**, **Vivianna Van Deerlin**, **Dara Aisner**, **Phillip Ruiz**, Gretchen Schaefer Johns, **Maria Bettinotti** and **Andrea Ferreira-Gonzalez**. A number of members from AMP and other organizations co-signed the letters. Several patient advocacy groups also wrote separate letters in support of broader coverage: Fragile X Foundation, Alpha-1 Foundation, SADS (Long QT). **The next phase of advocacy will be at the national CMS.**

- The Economic Affairs Committee will soon release a **survey to ascertain the extent of payment denials**. Please respond to that survey with as much information as possible.
- AMP submitted comments regarding **concerns with the CMS CY2014 Proposed Physician Fee Schedule (PFS) Rule** that was announced on July 18, 2013. The comment period for the Proposed Rule closed on September 6, 2013. The Final Rule is expected to be published on or around November 1, 2013, and new rates will be effective beginning January 1, 2014. The Rule includes a provision to bundle tests and cap reimbursement for certain services in the PFS at the Outpatient Prospective Payment System (OPPS) rates for 2013. AMP joined seven other pathology organizations to provide an initial response in August regarding general concerns with the **impact this rule could have to patient access to testing**. Both letters can be read here: http://www.amp.org/publications_resources/position_statements_letters/2013AMPPositionStatements.cfm
- AMP physician members are again reminded of the **importance of using the G0452-26 HCPCS code** when you provide a professional interpretation of a molecular pathology test. For more information

EDUCATION



• The **AMP 2013 Annual Meeting** is coming up quickly! Advance registration is open until October 15. View the preliminary program online now at: http://www.2013amp.org/preliminary_program.cfm
 Register and secure your housing today at: <http://www.2013amp.org/index.cfm>

• The **AMP 2013 Molecular Pathology Outreach Course**, *AMPlicons: A Practical Molecular Toolkit and Case Studies*, will be offered a day prior the AMP 2013 Annual Meeting in Phoenix. 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 from the **"Molecular Pathology/Molecular Diagnostic Toolkit."** For details, visit: <http://www.2013amp.org/mpoc/>.

• **The AMP Molecular Genetic Pathology (MGP) Review – Online Self-Study Course** is now available! The Course provides the audio-synchronized PowerPoint presentations of the "live" course that was offered in April 2013. To register or to obtain more information, visit: <http://www.amp.org/mgp2013/>.

• **What are your educational needs** that AMP can fulfill? Be on the lookout for the annual online survey. Your participation and feedback are critical and valued in helping AMP address those needs in its educational programs. Results and discussions will be held at a specialty lunch during the AMP 2013 Annual Meeting facilitated by **Laura J. Tafe** and others from the Training & Education Committee.

• **AMP at ASCP 2013:** **Ted Schutzbank**, **Annette Kim**, and **Kathy Mangold** will be presenting a Molecular Diagnostics Primer course at the ASCP 2013 Annual Meeting on September 18 in Chicago, IL. For more information, visit: <http://www.ascp.org/2013-Annual-Meeting/index.html>. While you're there, stop by the AMP booth (#527) in the ASCP exhibit hall and enter to win a free year of membership!

• **AMP Webinar Series presents...**

Incidental Findings in the Era of Whole Exome Sequencing: A View from the Laboratory, September 17 at 1:00pm (ET). Presented by **Sherril J. Bale**, PhD (GeneDx) and hosted by **Rong Mao**, MD (ARUP), AMP Training & Education Committee Member. [Register now](#).

Applications of Human Genetic Testing in the Treatment of Infectious Diseases, October 10 at 1:00pm (ET). Presented by AMP Training & Education Committee Chair, **Ted E. Schutzbank**, PhD (Covance) and hosted by **Rangaraj Selvarangan**, BVSc, PhD, AMP Training & Education Committee Member. [Register now](#).

NGS Applications in Infectious Diseases, December 13 at 1:00pm (ET). Presented by Noah Hoffman, MD, PhD (Univ of Washington) and hosted by **Rangaraj Selvarangan**, BVSc, PhD, AMP Training & Education Committee Member. [Register now](#).

To register and view additional information about any of the AMP upcoming webinars, visit: http://www.amp.org/Webinars/future_webinars.cfm

• **AMP Case Reports in CAP TODAY...**

Multilocus Sequencing for Rapid Identification of Molds, February 2013
 Desiree Marshall, MD; Dhruva J. SenGupta, PhD; Daniel R. Hoogstraal, MB(ASCP); **Karen Stephens**, PhD; **Brad T. Cookson**, MD, PhD; and **Cecilia C.S. Yeung**, MD

Download the report: http://www.amp.org/publications_resources/documents/CAP_TODAY-

regarding the specific requirements CMS provided for billing the professional interpretative component for molecular diagnostic testing please review the [CHAMP Open Forum post by Mary Williams on August 26](#).

- The AMA Molecular Pathology Advisory Group is **currently developing CPT code proposals** based on the AMP proposal for genomic sequencing procedures in time for the next submission deadline (October, 28) to the AMA CPT Editorial Panel. **Elaine Lyon, Vicky Pratt, Aaron Bossler, Roger Klein, Maria Bettinotti and David Wilkinson** are all serving on the **AMA Molecular Pathology Advisory Group**.
- AMP continues to provide recommendations to the **CAP Pathology Coding Caucus (PCC)** for needed new molecular pathology CPT codes. The CAP PCC is the first step in developing new pathology CPT codes. **Jan Nowak** is AMP's representative.
- **LDT White Paper:** AMP continues to work with the FDA to educate officials about clinical laboratory practices and operations, and has emphasized the infeasibility of mandating the use of specific assays with particular drugs because of the multiplicity of potential drugs and assays platforms. Additionally, LDTs offer important benefits to patients through the rapid introduction of assays in response to new medical discoveries, enhanced flexibility in performance due to the ability to continually modify assays, and increased innovation stemming from the relative ease in incorporating new test methods and knowledge. AMP will continue to work diligently with FDA on this issue in order to achieve the **best outcomes for our patients**. The LDT Working Group white paper that addressed the complexities involved with oversight of LDTs was submitted to JMD and is in the peer review process.
- AMP responded to the **Presidential Commission for the Study of Bioethical Issues'** request for public comment on the ethical, legal, and social issues raised by incidental findings that arise from genetic and genomic testing, imaging, and testing of biological specimens conducted in the clinical, research, and direct-to-consumer contexts. AMP offered its expertise to assist in the Commission's efforts and encouraged the Commission to review guidelines and statements from pathology and genetic professional societies engaged in the practice of genomic medicine. AMP believes **genetic testing is best pursued in a medical setting** in which pre-test and post-test genetic counseling are available. The likelihood of incidental findings and the reporting dilemmas they entail presents yet another argument in support of this position, and argues against the advisability of direct-to-consumer large-scale genetic testing.
- AMP commented on the New FDA draft guidance for **Management of Cybersecurity in Medical Devices** indicating that while recognizing the importance of cybersecurity for electronic medical records, diagnostics instrumentation and test systems, standards should not prevent qualified professionals from utilizing, maintaining, and/or repairing the systems.
- AMP submitted comments on the FDA Draft Guidance on **Molecular Diagnostic Instruments with Combined Functions**. AMP believes this is a step forward in that FDA is formalizing the use of open channels on instruments. View the comments online at: http://www.amp.org/publications_resources/position_statements_letters/2013AMPPositionStatements.cfm
- The **Sunshine Act** took effect on August 1st. CMS held a webinar Aug. 8 to review the new rules and you can find the slide deck here: <http://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2013-08-07NPC-OpenPayments.pdf> AMP is working with exhibitors to facilitate compliance with the new rules.
- AMP continues to monitor **federal restrictions on employee travel**, and to advocate for a legislative exemption for conferences, the primary purposes of which are scientific collaboration and medical education.
- **Capitol Hill:** On July 11, 2013, AMP and ACLU held a **briefing to educate members of Congress** on the AMP v. Myriad Genetics United States Supreme Court decision. It was very well attended. On the same day, PRC Chair **Roger Klein** and AMP Government Relations Consultant Jennifer Leib visited with a number of congressional staff members.
- As of September 1, AMP is a sponsoring member of the **IOM Roundtable on Translating Genomic-Based Research for Health**. **Vicky Pratt** will represent AMP on the Roundtable.
- AMP became a member of the Federation of American Societies for Experimental Biology (FASEB) on July 1. **Greg Tsongalis** has been appointed to AMP's seat on **FASEB's Board of Directors** and will

[0213-Molecular_Pathology_Case_Report.pdf](#)

Take the self-test:

http://www.amp.org/publications_resources/Feb2013caserevQnA.cfm

Importance of Screening for Lynch Syndrome in Patients with EC, August 2013

Erik G. Jensen, MD; **Gregory J. Tsongalis**, PhD; and **Laura J. Tafe**, MD

Download the report:

http://www.amp.org/publications_resources/documents/657-AMP.pdf

Take the self-test:

http://www.amp.org/publications_resources/Aug2013caserevQnA.cfm

The **call for case reports** is ongoing. Visit the following page online for more information: http://www.amp.org/publications_resources/documents/CallforCaseReviewsV2.pdf

INNOVATION & IMPROVED PATIENT CARE



• The Co-Chairs and Expert Panelists on the **ASCP/CAP/AMP Clinical Practice Guidelines Development Group for the Evaluation of Molecular Markers for Colorectal Cancer** recently met in Houston to launch the literature review phase of the project. The representatives for AMP are **Antonia Sepulveda** (Co-Chair), **Federico Monzon**, **Shuji Ogino**, and Noralane Lindor.

• **Vicky Pratt** recently attended and represented AMP at the National Institute of Standards and Technology (NIST) **Genome in a Bottle Consortium Workshop**: <http://genomeinabottle.org/>. The Consortium consists of four working groups that span from (a) selecting and designing reference materials, (b) bioinformatics, data integration, and data representations, (c) measurements for reference material characterization, and (d) performance metrics. AMP will continue to work with the NIST Consortium to ensure that the true reference sequence is a usable reference standard for assay calibration and lab validation. The release of the whole genome Reference Material is planned for February 2014.

• **Recent AMP Reports in *The Journal of Molecular Diagnostics*...**

The Role of MGMT Testing in Clinical Practice summarizes the existing data that support the rationale for MGMT promoter methylation testing and possibly other molecular testing in clinically defined glioma subtypes. Authored by **Milena Cankovic, Marina N. Nikiforova, Matija Snuderl**, Adekunle M. Adesina, **Neal Lindeman**, Patrick Y. Wen, and Eudocia Q. Lee. (September 2013). For the full report, visit:

<http://www.journals.elsevierhealth.com/periodicals/jmdi/article/S1525-1578%2813%2900112-8/abstract>

Laboratory Practice Guidelines for Detecting and Reporting JAK2 and MPL Mutations in Myeloproliferative Neoplasms, provides recommendations and guidelines for laboratory practice for detection of mutations in the *JAK2* and *MPL* genes. Authored by **Jerald Z. Gong, James R. Cook, Timothy C. Greiner, Cyrus Hedvat, Charles E. Hill, Megan S. Lim, Janina A. Longtine, Daniel Sabath**, and **Y. Lynn Wang**. (November 2013). For the full report, visit: <http://www.journals.elsevierhealth.com/periodicals/jmdi/article/S1525-1578%2813%2900131-1/abstract>

For information about **submitting a manuscript to JMD**, visit: <http://www.journals.elsevierhealth.com/periodicals/jmdi/authorinfo>.

serve as AMP's initial representative on the Science Policy Committee.

- In July, AMP joined 70 other organizations as a founding partner to create a global alliance that will enable **responsible sharing of genomic and clinical data**.
- AMP continues to participate in a variety of policy discussions with other professional societies, laboratory groups, as well as coalition groups such as the **Personalized Medicine Coalition**.
- **Industry Members:** An Industry Member Advisory Group is being formed to assist the Professional Relations Committee to respond to FDA draft guidances to industry and other issues of importance to AMP industry members. Information on how to participate in the Advisory Group will be available soon via CHAMP.

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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